# ASSESSMENT OF COMMUNITY PHARMACISTS' KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVERSE DRUG REACTIONS REPORTING IN BENIN CITY, EDO STATE.


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## CERTIFICATION

This is to certify that this project work was carried out by **OGHENEKARO VICTOR UV**O with matriculation number **PHA1808471** in the Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmacy, University of Benin, Benin-City, in partial fulfillment of the requirements for the award of Doctor of Pharmacy (Pharm.D) degree.

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## DEDICATION

This project work is dedicated to God Almighty for His grace, mercies, direction and provision throughout the course of this study and to my family for their unwavering love, support, and encouragement throughout my academic journey. Their belief in me has been my greatest motivation.

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## ABSTRACT

**BACKGROUND**: Adverse drug reactions (ADRs) are unintended, harmful responses to medications at normal therapeutic doses causing significant morbidity, mortality and healthcare costs. Effective pharmacovigilance (PV) is essential for detecting, assessing and preventing ADR. Reporting of ADRs by healthcare professionals is vital for the success of pharmacovigilance. Community Pharmacists play a key role in ADR reporting but underreporting remains a serious issue. This study focuses on assessing the knowledge, attitude and practice of ADR reporting among community pharmacists in Benin City.

**OBJECTIVES:** This study was carried out to assess the knowledge, attitudes and practice of community pharmacists in adverse drug reactions reporting.

**METHODS**: After obtaining ethical approval from the Faculty of Pharmacy Ethics Committee, a cross sectional study was employed. The study employed the use of a structured questionnaire as the major instrument of data collection. The questionnaire was carefully developed to address the objectives of the study and distributed to licensed community pharmacists. The data obtained was analyzed using the software, SPSS version 29.

**RESULTS**: From the study conducted, a total of 184 community pharmacists participated, of which 65.4% were males while 34.6% were females. The result showed an encouraging awareness levels of community pharmacists to pharmacovigilance and adverse drug reactions (ADRs) reporting practices. Almost all respondents (98.9%) acknowledged that ADRs should be reported by community pharmacists and recognized the importance of such reporting for patient safety. Poor knowledge about drug-induced diseases was evident in only 11% of participants while 52% demonstrated good knowledge. Attitudes were primarily positive (78%) and practices

were categorized as good for 7%, fair for 27% and poor for 66% of pharmacists. The top five reported barriers to ADR reporting were unavailability of ADR forms (27%), uncertainty about causality (13.7%), lack of time/workload (12.3%), no rewards for reporting (9.7%), and complexity of the reporting form (8.7%).

**CONCLUSION**: The findings of this study revealed that community pharmacists in Benin City had an encouraging awareness level to pharmacovigilance and ADR reporting practices, a good knowledge of drug-induced diseases, and demonstrated a positive attitude towards ADR reporting but consistent ADR reporting was still below expectations. Thus, there is poor reporting of adverse drug reactions (ADRs) by community pharmacists in Benin City.

**KEYWORDS**: Adverse drug reaction, pharmacovigilance, knowledge, attitude, practice, community pharmacists.

**TABLE OF CONTENTS**

## LIST OF TABLES

## LIST OF FIGURES

# CHAPTER ONE

# INTRODUCTION

## 1.1: BACKGROUND OF STUDY

Adverse drug reactions (ADRs) are unintended and harmful responses to a medicine that occur at normal therapeutic doses used for disease prevention, diagnosis, treatment or modification of physiological functions (WHO, 2020). ADRs may present as mild, moderate, or severe symptoms, and in some cases, they can be life-threatening or fatal. They are a major cause of morbidity and mortality worldwide and have been recognized as a public health concern, contributing to increased hospital admissions, prolonged admission in hospitals, therapeutic failures, and higher healthcare costs.

Pharmacovigilance refers to the science and activities associated with the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems (WHO, 2020). This is carried out to ensure continuous monitoring of drug safety after medications are introduced into the market. Since clinical trials often involve relatively small populations and controlled conditions, many ADRs may not be identified until a drug is in widespread use. Pharmacovigilance systems are therefore essential in identifying safety concerns early and informing regulatory actions that help protect public health.

The causes of ADRs are often complex and multifactorial. They may be influenced by individual patient characteristics such as age, sex, genetic differences, comorbidities, or concurrent medications. Other contributing factors include drug-drug interactions, inappropriate prescribing, self-medication, poor adherence to treatment, and dispensing errors. Populations such as the elderly, children, and individuals with chronic conditions are particularly vulnerable to adverse drug reactions. ADRs occur across all levels of healthcare, including hospitals, clinics, and

especially community pharmacies. In many developing countries, including Nigeria, community pharmacists are among the most accessible healthcare professionals and often serve as the first point of contact for medication-related issues. However, the recognition and documentation of ADRs are often inconsistent or completely absent. This tends to hinder the effectiveness of the national pharmacovigilance system and undermines the overall goal of medication safety.

The burden of adverse drug reactions both globally and locally have been shown by previous studies. It was reported that ADRs were responsible for up to 6.7% of hospital admissions in the United States and were one of the leading causes of death among hospitalized patients (Lazarou et al. 1998). In Nigeria, it was found that high incidence of ADRs occurred among inpatients in a tertiary hospital (Akhideno et al 2018) while in pediatric patients, frequent adverse drug reactions were identified, particularly due to antimalarials and antibiotics (Oshikoya et al. 2011). It was also noted that a significant proportion of ADRs in Nigerian hospitals went unreported (Oladapo et al. 2020) which points to the need for stronger pharmacovigilance practices.

The recognition of ADRs often relies on the clinical judgment of healthcare providers, involving a combination of clinical awareness and observation. Pharmacists are in a unique position to detect possible ADRs through direct patient communication and treatment monitoring. Common signs include new symptoms following the initiation of a drug, worsening of existing conditions, or unexpected laboratory findings. For instance, a patient who begins to experience itching, rash, or fatigue shortly after starting a new medication may be showing early signs of an adverse reaction. Other indicators include unexplained changes in blood pressure, blood glucose, liver enzymes, or discontinuation of therapy due to intolerable side effects. Pharmacists can also identify ADRs through complaints of dizziness, swelling, gastrointestinal disturbances, or allergic responses. Being alert to these signs and verifying patient history can significantly

improve early detection and intervention. However, despite their training and strategic position in the healthcare system, community pharmacists in Nigeria are often underutilized in ADR reporting.

ADR reporting is a key component of pharmacovigilance. The World Health Organization have encouraged all healthcare professionals to report suspected ADRs, regardless of certainty of cause. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) oversees the pharmacovigilance program and has implemented tools like the Yellow Card and Med Safety App to facilitate spontaneous reporting but the actual number of reports submitted by pharmacists remains low. Previous studies have revealed that only 27% of Nigerian community pharmacists had ever reported an ADR (Afolabi et al. 2021). This lack of participation may be due to factors such as limited awareness, fear of professional liability, absence of feedback from regulators, and uncertainty about what constitutes a reportable reaction.

Failure to report ADRs carries serious implications. This is because, when adverse reactions go unreported, harmful drugs may remain in circulation longer than they should, putting more patients at risk. Regulatory agencies will then be unable to make informed decisions, such as issuing warnings or withdrawing unsafe products, without reliable data. Additionally, poor reporting practices hinder research and limit the availability of safety information for both professionals and the public. Pharmacists who do not engage in pharmacovigilance often miss a critical opportunity to improve patient care and contribute to safer medication use.

This study therefore seeks to assess the knowledge, attitude and practice of adverse drug reactions reporting by community pharmacists in Benin City, Edo State.

## 1.2: DEFINITION AND CLASSIFICATION OF ADVERSE DRUG REACTIONS (ADRs)

An important component of pharmacovigilance and drug safety monitoring are adverse drug reactions (ADRs). "A reaction to a medication which is unpleasant and unexpected, and which happens at dosages typically used in humans for the prevention, diagnosis, or treatment of disease, or for the alteration of physiological function" is the definition provided by the World Health Organization (WHO, 2002). This definition only considers harm resulting from routine clinical use, excluding overdose, drug abuse, and therapeutic failures.

ADRs raise healthcare costs worldwide, lengthen hospital stays, and increase patient morbidity, which makes them a serious concern. Some adverse drug reactions (ADRs) are minor and self-limiting, but others can cause major problems or even death, particularly if they go unnoticed or unreported (Edwards and Aronson, 2000). ADRs are frequently categorized according to their mechanism, severity, predictability, and timing in order to guarantee clarity and enhance reporting. Key categories pertaining to clinical practice and pharmacovigilance are listed below:

### Classification Based on Mechanism

The Rawlins and Thompson classification, which initially separated ADRs into two primary categories before adding additional sub-categories, is among the most widely used systems.

1. Type A (Augmented): These are dose-dependent, predictable reactions based on the known pharmacological action of the drug. They are usually less severe but more frequent. E.g Hypoglycaemia caused by insulin or bleeding due to warfarin (Edwards and Aronson, 2000).

2. Type B (Bizarre): These are uncommon, unpredictable, not dose-related, and often involve hypersensitivity or idiosyncratic responses. E.g Anaphylaxis following penicillin use or Stevens-Johnson syndrome with sulfonamides.

3. Type C (Chronic): Related to long-term use of a drug. E.g Adrenal suppression from prolonged corticosteroid use.

4. Type D (Delayed): Occur after a prolonged period, even after discontinuation. E.g Carcinogenesis from cytotoxic drugs or teratogenicity from thalidomide.

5. Type E (End-of-use): Associated with drug withdrawal. E.g Rebound hypertension after stopping clonidine abruptly.

6. Type F (Failure): Involves therapeutic failure, sometimes due to drug interactions or resistance. E.g Ineffectiveness of antibiotics due to microbial resistance.

**Classification Based on Severity**

1. Mild ADRs: No major treatment or hospitalization required, for example Dry mouth from antihistamines.

2. Moderate ADRs: Require changes in therapy, such as dose reduction or additional treatment. For example, Nausea requiring antiemetic therapy due to chemotherapy.

3. Severe ADRs: Life-threatening, cause disability, hospitalization, or death. E.g Torsades de pointes from some antiarrhythmics.

**Classification Based on Predictability**

1. Predictable ADRs: Related to pharmacological properties; usually Type A. E.g Sedation from benzodiazepines.

2. Unpredictable ADRs Immune-mediated or idiosyncratic; usually Type B. E.g Drug-induced lupus from hydralazine.

**Classification Based on Time of Onset**

1. Acute ADRs: Occur within one hour. An example is the Anaphylaxis post-injection.

2. Subacute ADRs: Occur within a day to several weeks. For example, drug-induced hepatotoxicity.

3. Latent ADRs: Appear after prolonged use.

Example: Osteoporosis due to long-term corticosteroids.

### 1.2.1: DISTINCTION BETWEEN ADVERSE DRUG REACTIONS AND SIDE EFFECTS

The terms "side effect" and "adverse drug reaction (ADR)" are frequently used interchangeably in academic and clinical contexts. These terms, however, have different meanings and connotations, especially when it comes to patient safety, regulatory obligations, and pharmaceutical monitoring. In order to effectively identify, interpret, and report drug-related issues, healthcare professionals including community pharmacists, must have a thorough understanding of their differences.

An adverse drug reaction is "a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function," according to the World Health Organization (WHO, 2020). This definition is specific and relates only to harmful and unintended reactions that arise during normal clinical use. ADRs are undesirable by nature and usually call for additional treatment, a change in therapy, or even hospitalization or death. On the other hand, a side effect is generally defined as a secondary, typically predictable effect of a drug that occurs in addition to its intended therapeutic effect. According to the U.S. Food and Drug

Administration (FDA, 2022), side effects are usually known and documented during clinical trials and may be beneficial, neutral, or harmful. They do not necessarily warrant discontinuation of the drug unless they become intolerable or life-threatening. For example, drowsiness caused by antihistamines or gastrointestinal discomfort associated with antibiotics are common side effects. Thus, while all ADRs are unintended and harmful, not all side effects meet this criterion. Some side effects may be benign or even desirable in specific cases such as weight gain from antipsychotics being beneficial for underweight patients.

There are important clinical and regulatory ramifications to distinguishing ADRs from side effects. Because ADRs may reveal unidentified medication risks or detrimental interactions, they usually need to be formally reported to pharmacovigilance centers. Through this reporting, regulatory bodies like the FDA in the US, WHO Uppsala Monitoring Centre, and NAFDAC in Nigeria can assess the safety profile of pharmaceuticals and take appropriate action, such as removing drugs from the market, limiting their use, or issuing safety alerts (WHO, 2002).

Side effects, although important might not always require reporting unless they are severe, unexpected, or have a substantial impact on the patient's quality of life. Prescribers or pharmacists typically warn patients about side effects beforehand, and they are typically listed in the drug's product leaflet or summary of product characteristics (SmPC). Another significant difference is that ADRs can include uncommon or erratic reactions, like drug-induced liver damage or anaphylaxis, which are frequently Type B reactions (bizarre or idiosyncratic). The drug's known pharmacological action, on the other hand, causes side effects, which are typically Type A reactions (augmented and dose-dependent) (Rawlins & Thompson, 1977; Edwards & Aronson, 2000).

Examples to show this distinction will include:

A. Paracetamol (acetaminophen):

Side effect - Mild nausea or rash.

ADR - Acute liver failure due to normal-dose hepatotoxicity in susceptible individuals.

B. Amoxicillin:

Side effect - Mild diarrhea.

ADR - Stevens-Johnson Syndrome (a rare but serious hypersensitivity reaction).

C. Insulin:

Side effect - Mild weight gain.

ADR - Severe hypoglycemia requiring emergency care.

These examples show that side effects are typically expected and manageable, whereas ADRs often require immediate clinical attention and may have severe consequences. However, reporting practices and community pharmacists are implicated in this. For community pharmacists to effectively educate patients, make therapeutic decisions, and report pharmacovigilance, they must be able to distinguish between side effects and adverse drug reactions. The integrity of drug safety data can be compromised by either overreporting expected outcomes or underreporting serious reactions when side effects are mislabeled as adverse drug reactions (ADRs) or vice versa. Pharmacists should also advise patients on which reactions to report and promote prompt feedback, particularly when it comes to recently prescribed drugs. Routine side effects are appropriately managed without needless therapy discontinuation, and

serious ADRs are identified and promptly addressed due to effective documentation and communication.

### 1.2.2: PREVALENCE OF ADVERSE DRUG REACTIONS

Adverse drug reactions (ADRs) are a serious public health concern with widespread implications for healthcare systems and patient safety. Their impact is seen in increased rates of hospital admissions, extended hospital stays, and avoidable deaths. Understanding the scope of ADRs both globally and within individual countries is essential for building effective pharmacovigilance systems, shaping healthcare policies, and introducing targeted interventions especially in countries like Nigeria, where pharmacovigilance systems are still maturing.

Globally, numerous studies have shown that ADRs significantly contribute to hospital admissions. In the United Kingdom, for example, research suggested that about 6.5% of hospitalisations could be traced back to ADRs, with many considered preventable (Pirmohamed et al., 2004). Data from other developed nations have placed this figure between 5% and 10%, highlighting a persistent challenge (Formica et al., 2018). Among hospitalised patients, ADRs are not uncommon, with occurrence rates ranging from 10% to 20%, especially among older adults and individuals taking multiple medications (Tangiisuran et al., 2015). According to the World Health Organization (WHO, 2020), up to one in five inpatients may experience at least one ADR during their hospital stay, underlining the importance of continuous drug safety surveillance in both inpatient and outpatient settings.

In many low- and middle-income countries, the situation appears even more challenging. Limitations in pharmacovigilance systems, weak infrastructure, and lack of awareness among healthcare professionals often contribute to poor ADR monitoring and widespread

underreporting. A systematic review conducted by Alomar et al. (2020) noted that the true burden of ADRs in developing regions remains underestimated due to gaps in spontaneous reporting and limited institutional capacity for pharmacovigilance activities. These constraints not only delay the identification of drug safety issues but also prevent policymakers from making informed decisions based on local evidence.

In Nigeria, the available evidence points to a worrying trend. Though comprehensive national data is limited, regional studies suggest that ADRs are a notable cause of hospital admissions. A retrospective review found that ADRs were responsible for roughly 10.5% of hospitalisations in Nigeria, higher than the global average (Oshikoya et al., 2011). At a northern Nigerian teaching hospital, 6.7% of older adult inpatients were reported to have experienced at least one ADR, with commonly implicated drugs including antibiotics and antihypertensives (Nwani and Isah, 2017). Similarly, research in Lagos State identified ADRs in 10.7% of hospitalised adult patients, while 1.2% of paediatric inpatients were also affected (Akhideno et al., 2018). Though the paediatric figure appears modest, it may not reflect the full extent of the problem due to the diagnostic complexities involved in children.

Despite the evident risks, pharmacovigilance systems in Nigeria remain underutilised. The National Pharmacovigilance Centre (NPC), operating under the National Agency for Food and Drug Administration and Control (NAFDAC), has introduced initiatives like the Yellow Card reporting scheme to encourage spontaneous ADR reporting. However, reporting rates are far from optimal. In 2024, for example, Nigeria logged just 4,600 ADR reports which is only 10% of the WHO-recommended minimum of 200 reports per million population, based on the country's estimated population size (Edema, 2025). This discrepancy points to widespread underreporting, which limits the country's ability to detect drug-related risks early and act swiftly.

Several barriers have been identified as contributors to this underreporting trend. These include low awareness of the reporting process, inadequate training, limited access to reporting forms, and the belief among some healthcare professionals that only severe reactions merit documentation (Ogunleye et al., 2014; Osei et al., 2021). Community pharmacists, who are often the first point of contact for many patients, are particularly relevant in this regard. While their awareness of ADRs is generally good, actual reporting behaviour remains suboptimal. For example, a study conducted in Lagos found that only 24.2% of community pharmacists had ever submitted an ADR report, despite more than 80% being familiar with the Yellow Card system (Olugbake et al., 2023).

Special attention is also needed for high-risk populations such as the elderly and individuals living with chronic illnesses. Polypharmacy and age-related changes in drug metabolism place older adults at increased risk of experiencing ADRs. A national study revealed that the prevalence of ADRs among older Nigerians ranged from 4.4% to 31.1%, depending on clinical setting and type of medications used (Ufuah et al., 2024).

Since long-term medications are usually initiated and monitored in primary care and community pharmacy settings, these findings points to the importance of stepping up pharmacovigilance efforts in these settings.

### 1.2.3: PHARMACOVIGILANCE SYSTEMS AND ADVERSE DRUG REACTIONS REPORTING

Pharmacovigilance is all about keeping medicines safe after they've been approved for use. It involves a combination of scientific methods and structured activities designed to detect, assess, understand, and prevent any unwanted effects or other medicine-related issues (WHO, 2020). While clinical trials help uncover many potential side effects before a drug hits the market, they

can’t catch everything. Trials often include relatively small groups of people and may exclude important segments of the population such as older adults, pregnant women, or those with complex health conditions. Real-world use, therefore, can reveal additional problems that weren't apparent in the controlled settings of pre-marketing studies (Edwards and Aronson, 2000).

This is where post-marketing surveillance becomes essential. Once a drug is available to the public, pharmacovigilance systems step in to monitor how it performs under everyday conditions. One of the core tools used in this process is spontaneous reporting, which is a method that allows healthcare professionals, and increasingly, patients, to report any suspected adverse drug reactions (ADRs). These reports are crucial for spotting early warning signs about drug safety and can prompt regulatory agencies to take decisive actions, such as updating safety information, restricting use, or even withdrawing a drug altogether if necessary (EMA, 2021).

Most countries operate pharmacovigilance systems under the oversight of national drug regulatory bodies. On a global scale, the World Health Organization (WHO) has led this effort since 1968 through its Programme for International Drug Monitoring. This initiative brings together over 170 countries that share data and collaborate on medicine safety. At the core of this program is VigiBase, a vast international database that collects individual case safety reports from participating nations. It is managed by the Uppsala Monitoring Centre in Sweden and serves as a global hub for pharmacovigilance data (UMC, 2022).

Each country that participates in this program typically runs a National Pharmacovigilance Centre. These centres collect local ADR reports, train healthcare providers on how to report effectively, analyse safety data, and feed relevant information into the global VigiBase system.

Tools such as yellow card forms, online portals, and mobile apps are commonly used to make reporting more accessible and user-friendly.

Pharmacovigilance also operates across regional and continental platforms. In Europe, for instance, the European Medicines Agency (EMA) manages EudraVigilance, a system that centralizes safety data for EU member states (EMA, 2021). On the African continent, efforts are underway to establish the African Medicines Agency (AMA), a body designed to harmonize drug regulatory practices across member states with pharmacovigilance as a key priority.

At its core, ADR reporting is a public health safeguard. It helps flag unknown or evolving risks associated with medications and supports evidence-based decisions that can protect patients. Effective reporting enables regulators to re-evaluate a drug's risk-benefit profile, share critical safety updates with healthcare providers and the public, and improve how medicines are prescribed and used. It also helps pinpoint specific risk factors or vulnerable patient groups who may be more likely to experience adverse reactions (Edwards et al., 2012). The major aims of ADR reporting include identifying new or uncommon side effects, especially those that are severe; reassessing the safety of medicines already on the market; ensuring that important safety messages reach both clinicians and patients; and ultimately, improving prescribing practices through more informed guidance. It also supports identifying people at greater risk, allowing for better individualization of treatment.

Over the past two decades, Nigeria has made considerable progress in developing its pharmacovigilance system, although significant gaps remain in its implementation. Oversight for pharmacovigilance activities falls under the responsibility of the National Agency for Food and Drug Administration and Control (NAFDAC), which established the National

Pharmacovigilance Centre (NPC) in 2004 as a specialised unit for managing adverse drug reaction (ADR) data. This centre also connects Nigeria to the global pharmacovigilance community through its contributions to the World Health Organization's Programme for International Drug Monitoring (WHO-PIDM) and the international VigiBase database maintained by the Uppsala Monitoring Centre in Sweden (UMC, 2022). One of the central components of Nigeria's pharmacovigilance strategy is the Yellow Card Scheme. This system enables spontaneous reporting of suspected ADRs and encourages participation from a broad range of healthcare professionals, including pharmacists, doctors, and nurses. To enhance accessibility and efficiency, the reporting process can now be completed either on paper or through digital channels. The introduction of the Med Safety App, developed through a collaboration between WHO and UMC, marks a significant step forward in facilitating easier ADR reporting using mobile devices (NAFDAC, 2023).

### 1.2.4: BENEFITS OF ADVERSE DRUG REACTION REPORTING IN PATIENT SAFETY

Pharmacovigilance mainly depend on the reporting of adverse drug reactions (ADRs). By identifying and addressing potential safety concerns, ADR reporting improves overall healthcare outcomes and promotes patient safety. The benefits of reporting adverse drug reactions (ADRs) include the following but are not restricted to the same: improved patient safety, heightened pharmacovigilance, better decision-making, the ability to identify rare or long-lasting side effects, safer drug development, and a decreased burden of ADRs etc.

1. Improved Patient Safety: The enhancement of patient safety is the main advantage of ADR reporting. Healthcare providers can prevent harm and enhance patient outcomes by quickly addressing possible safety issues with medications (World Health Organization, 2019). This

entails modifying treatment regimens, keeping a closer eye on patients, and informing them of potential hazards. Healthcare providers can lower the risk of adverse reactions and deliver more effective care by reporting ADRs. Additionally, ADR reporting assists in identifying potentially harmful medications, enabling medical professionals to take action to stop additional harm. This can involve withdrawing drugs from the market, sending out safety warnings, or even changing the labels of medications (Pirmohamed et al., 2004). ADR reporting helps to guarantee that patients receive the best care possible by putting patient safety first.

2. Enhanced Pharmacovigilance: The science of tracking medication safety and identifying possible safety issues is known as pharmacovigilance. Because it offers useful information that can be used to spot patterns and trends in medication-related harm, ADR reporting is an essential part of pharmacovigilance (European Medicines Agency, 2020). Healthcare practitioners and regulatory organizations can create more potent plans for averting ADRs and enhancing medication safety by examining ADR data. Because ADR reporting offers a more thorough understanding of medication safety, it improves pharmacovigilance. This entails finding uncommon or persistent adverse effects, spotting possible safety issues with particular drugs or drug classes, and creating more efficient techniques for keeping an eye on drug safety (Hazell & Shakir, 2006). ADR reporting contributes to improved pharmacovigilance, which guarantees the safe and efficient use of pharmaceuticals.

3. Informed Decision-Making: ADR reporting offers useful data that helps regulators make decisions regarding pharmaceuticals. To make well-informed decisions regarding medication approvals, labeling, and withdrawals, regulatory bodies consult ADR data (US Food and Drug Administration, 2020). This entails removing drugs from the market if they are judged to be too dangerous, modifying dosage recommendations to reduce risk, and updating medication labels to

reflect new safety information. Healthcare providers can assist regulatory agencies in making decisions that put patient safety first by supplying timely and accurate ADR data. This involves safeguarding patients from possible harm and making sure that drugs are used safely and effectively (Pirmohamed et al., 2004). Since ADR reporting offers the information required to make evidence-based decisions regarding medication safety, it is crucial for making well-informed decisions.

4. Identification of Rare or Long-term Side Effects: For the purpose of detecting uncommon or chronic drug side effects, ADR reporting is essential. These adverse effects might not be noticed in clinical trials and might only show up after a drug has been given the all-clear to be used (Hazell & Shakir, 2006). Healthcare practitioners can spot possible safety issues and take action to lessen harm by examining ADR data. Ensuring patient safety requires the identification of uncommon or chronic side effects. Healthcare providers can modify treatment regimens, increase patient monitoring, and inform patients about possible risks by identifying these side effects. ADR reporting contributes to the best possible care for patients and the timely resolution of any possible safety issues.

5. Safer Medication Development: Pharmaceutical companies benefit greatly from ADR reporting, which helps them create safer and more efficient drugs. Businesses can find possible safety issues and improve their drugs to reduce risk by examining ADR data (Davies et al., 2010). This entails creating safer and more efficient new drugs as well as enhancing current ones to lower the possibility of negative side effects. Innovation and advancement in drug development are fueled by ADR reporting. ADR reporting aids pharmaceutical companies in creating safer and more effective drugs by offering insightful information about medication safety. In the end, patients gain from this since they get better care and treatment choices.

6. Reduced Burden of ADRs: The burden of ADRs on patients, healthcare systems, and society at large can be lessened with the aid of ADR reporting. Healthcare providers can lower healthcare expenses related to ADRs and enhance patient outcomes by recognizing and resolving possible safety issues (Davies et al., 2010). This entails shortening hospital stays, lowering the need for extra care, and enhancing the quality of life for patients. ADR reporting can improve public health and well-being by lessening the burden of ADRs. This entails raising the general standard of care, lowering medical expenses, and improving patient outcomes. In order to lessen the burden of ADRs and guarantee that patients receive the best care possible, ADR reporting is crucial.

### 1.3: THE MODEL COMMUNITY PHARMACIST

Community pharmacists are among the most accessible healthcare professionals, which place them in a key position within modern healthcare systems. Beyond the traditional role of dispensing medications, the ideal community pharmacist is a patient-focused practitioner who combines clinical expertise with ethical responsibility, effective communication, and a strong commitment to public health. As healthcare needs continue to evolve, defining the model community pharmacist is important for promoting effective pharmaceutical care and improving patient outcomes.

A community pharmacist is a licensed professional who operates or practices in community-based settings such as retail pharmacies. Their responsibilities extend beyond medication dispensing to include health promotion and disease prevention. Unlike hospital or industrial pharmacists, community pharmacists maintain consistent, direct contact with the public and often serve as the first point of interaction within the healthcare system (Anderson et al., 2003). To manage the clinical, managerial, and interpersonal demands of their practice, they must

possess not only pharmaceutical knowledge but also strong organizational and communication skills.

Clinical knowledge remains a major advantage of community pharmacy practice. Being skilled in pharmacotherapy, drug interactions, and patient counseling is highly required. However, due to the rapid advancement of medications and treatment guidelines, continuous professional development is necessary to maintain up-to-date knowledge (FIP, 2021). Community pharmacists must accurately interpret prescriptions, identify potential medication-related problems, and provide evidence-based recommendations to both patients and prescribers. Furthermore, competence in emerging areas such as health screening, chronic disease management, and pharmacovigilance is increasingly important (Bailey et al., 2021).

Ethical practice is another defining attribute of the ideal community pharmacist. This includes the provision of services without discrimination, adherence to informed consent protocols, and the safeguarding of patient confidentiality. Given their access to sensitive health information, community pharmacists must handle such data with discretion and professionalism. Their decisions should be guided by the principle of beneficence, prioritizing patient well-being over personal or financial interests (Gidman et al., 2012). Effective communication and interpersonal skills are also central to pharmacy practice. These include active listening, simplifying complex medical information, and promoting medication adherence. In diverse communities, cultural sensitivity and multilingual communication are important for effective patient engagement. Building trust and rapport helps create an environment where individuals feel comfortable seeking health advice (Wirth et al., 2020).

A strong public health orientation further distinguishes the model community pharmacist. In addition to individualized care, pharmacists contribute to broader health initiatives such as immunization programs, responsible medication use, public health education, and screenings for conditions like diabetes, hypertension, and infectious diseases (Blenkinsopp et al., 2007). In rural areas, they often serve as key providers of primary healthcare services. Organizational and managerial competencies also form part of the ideal pharmacist's profile. Responsibilities such as staff supervision, inventory control, compliance with regulations, and record keeping are essential to ensuring the safety, quality, and efficiency of pharmaceutical services. Balancing these administrative duties with clinical responsibilities is highly necessary.

Technology has also become a vital aspect of pharmacy practice. The ideal community pharmacist blends digital tools such as electronic health records, drug interaction checkers, and telepharmacy platforms to enhance patient care. The COVID-19 pandemic accelerated the integration of such technologies, and pharmacists are increasingly expected to provide services like remote consultations and electronic prescriptions (Poudel & Nissen, 2016).

### 1.3.1: COMMUNITY PHARMACY STANDARDS

It is impossible to overstate how important it is for community pharmacies to uphold high standards of practice. These guidelines are intended to guarantee patients receive safe, efficient, and high quality services. These guidelines address everything from medication dispensing to patient counseling and business procedures. The profession is challenged by the requirement for community pharmacy standards to be continuously improved. A community pharmacy's requirements consist of, but are not restricted to, the following:

1. Patient Access: Patients must be able to gain access to the pharmacy.

2. Licensing and Compliance: Must obtain a license from the appropriate regulatory body and follow all federal, state, and local laws and regulations.

3. Employee Qualifications: All pharmacy employees must have the appropriate training and license.

4. Environment and Safety: The environment must be kept safe, tidy, and orderly.

5. Security Measures: Appropriate security measures must be implemented to safeguard pharmaceuticals and patient data.

6. Patient Privacy: Patient privacy must be protected.

7. Medication Storage: Needs to make sure that drugs are stored correctly, with the right temperatures maintained, and security for controlled substances provided.

8. Accurate Dispensing: Accurate medication dispensing must be guaranteed, including prescription verification, screening for drug therapy problems, and checking for possible drug interactions.

9. Record Keeping: All dispensed prescriptions must have accurate and current records kept, and drug therapy profiles and patient histories must be kept up to date.

10. Patient Counseling: Patients must receive counseling regarding the use of medications, their interactions, and side effects.

11. Medication Therapy Management: Medication therapy management services must be offered to assist patients in effectively managing their medications and medical conditions.

12. Continuity of Care: Procedures that guarantee continuity of care must be provided.

13. Inventory Control: Effective and efficient inventory control to avoid overstocking and shortages.

14. Quality Products: Needs to offer high-quality products at affordable prices.

15. Community Contribution: Needs to contribute to community health care.

16. Professional Environment: Must constantly work to maintain a professional environment for their patients and improve the image of the pharmacy.

17. Patient-Centered Care: Must deliver patient-centered care, putting the needs and welfare of patients first in all interactions and services.

### 1.3.2: RESPONSIBILITIES OF A COMMUNITY PHARMACIST IN PROMOTING PATIENT SAFETY

Community pharmacists are frequently the first people to be contacted when people need medical assistance because they are primary healthcare providers. They are therefore an important member of the pharmacovigilance team by virtue of their regular patient encounters, which allow them to efficiently monitor and report ADRs. Hence, the role community pharmacists play cannot be overlooked.These include:

1. Dispensing Medications: Pharmacists make sure patients are given the appropriate drugs, dosages, and duration of treatment. They check for possible interactions, go over prescriptions, and give patients advice on how to take them. By doing this, patients can avoid adverse drug reactions (ADRs) and make sure they get the most out of their medication (World Health Organization, 2019). Pharmacists manage medication therapy, which is essential to maintaining patients' health and safety. In order to optimize treatment, they also collaborate with patients to identify and resolve any medication-related issues, making necessary adjustments.

2. ADR Monitoring and Reporting: Pharmacists are taught to recognize possible adverse drug reactions (ADRs) and notify regulatory bodies about them (World Health Organization, 2002). This is to help monitor and stop similar reactions in the future, the pharmacist records the occurrence and submits a report whenever a patient reports a side effect or exhibits symptoms of an ADR. Pharmacovigilance is a process that depends on pharmacists to offer insightful information about the safety of medications. Pharmacists who report adverse drug reactions (ADRs) add to a larger database that aids regulatory bodies and medical professionals in making well-informed decisions regarding the safety of medications.

3. Patient Education: Pharmacists instruct patients on proper medication administration, warning signs of adverse effects, and when to seek medical help. Additionally, they offer details on possible interactions with other drugs, foods, or medical conditions. Pharmacists assist patients in actively managing their health and lowering the risk of adverse drug reactions by arming them with information. This instruction may cover discussions such as how to remember to take their medications on time, as well as how to store, handle, and dispose of medications.

4. Collaboration with Healthcare Teams: To improve patient care, pharmacists collaborate closely with physicians, nurses, and other medical specialists. They exchange details regarding drug schedules, possible ADR hazards, and mitigation techniques. Pharmacists contribute to ensuring that patients receive comprehensive care and that medication-related issues are quickly identified and resolved by working with healthcare teams. Reducing the burden of ADRs and delivering high-quality patient care depend on this teamwork.

5. Pharmacovigilance: Pharmacists are essential to pharmacovigilance because they keep an eye on the safety of medications and report any problems (European Medicines Agency, 2020). By

assisting in the identification of trends and patterns that may point to a more serious safety issue, they aid in the detection, evaluation, and prevention of ADRs. Pharmacists can improve patient safety and lower the risk of adverse drug reactions (ADRs) by taking part in pharmacovigilance initiatives, which assist regulatory bodies and medical professionals in making well-informed decisions regarding medication safety.

Because of their close proximity to patients, community pharmacists are a valuable source of information on adverse drug reactions (ADRs) (Alsulami et al., 25). Community pharmacists can make a substantial contribution to ADR reporting by utilizing their knowledge and patient-centered approach, which will ultimately enhance patient care. In order to support the continuous assessment of medication safety and to inform regulatory decisions, community pharmacists have an obligation to report adverse drug reactions (ADRs) to regulatory bodies (NAFDAC). Only roughly 27% of community pharmacists reported ADRs to the NPC in 2024, indicating a serious problem with underreporting (Alsulami et al., 2025). ADR reporting by community pharmacists has been found to be hampered by a number of factors, such as a lack of awareness and knowledge, a lack of drive, and inadequate regulatory agency feedback (Nduka, 2024; Shareef, 2024).

### 1.3.3: BARRIERS TO ADVERSE DRUG REACTION REPORTING BY COMMUNITY PHARMACISTS

Researchers and healthcare professionals have consistently acknowledged that community pharmacists, despite their accessibility and key role in medicine distribution, face various challenges when it comes to reporting Adverse Drug Reactions (ADRs). It was widely noted that although pharmacists are in a unique position to observe, identify, and act on ADRs, their actual contribution to pharmacovigilance systems remains suboptimal.

It was observed that lack of knowledge and awareness was a significant barrier. Pharmacovigilance experts pointed out that many community pharmacists lacked clear understanding of ADR definitions, reporting criteria, or appropriate procedures. Akunyili (2012) had earlier highlighted this deficiency, stressing that inadequate training left pharmacists ill-equipped to participate effectively in pharmacovigilance. Sweis and Wong (2000) had similarly found that a considerable number of pharmacists in Great Britain did not know where or how to report ADRs. In the Nigerian context, Oshikoya and Awobusuyi (2009) reported that pharmacists were unaware of key tools like the Yellow Card Scheme, further limiting their capacity to report.

In addition, studies revealed that workload and time constraints posed major limitations. Community pharmacies, often understaffed, left pharmacists juggling dispensing, inventory, and administrative duties. Lopez-Gonzalez, Herdeiro and Figueiras (2009) reported that many pharmacists found ADR documentation time-consuming and incompatible with their busy schedules. This claim was reinforced by findings from Oshikoya et al. (2012), who stated that over 60% of community pharmacists in Lagos admitted that lack of time discouraged them from submitting ADR reports.

Another challenge reported was uncertainty about causality. Many pharmacists reportedly felt hesitant to file a report unless they were sure that the drug in question caused the reaction. This misunderstanding, according to WHO (2002), contradicted global pharmacovigilance principles, which encourage the reporting of all suspected ADRs, not only confirmed ones. Toklu and Uysal (2008) added that pharmacists often feared making an error in judgment, which ultimately discouraged reporting.

It was also revealed that lack of feedback from regulatory authorities diminished motivation among community pharmacists. Lopez-Gonzalez et al. (2009) noted that when healthcare providers submitted ADR reports without receiving any form of acknowledgment, they tended to view the process as meaningless. Edema (2025) similarly found that Nigerian community pharmacists were discouraged due to the perceived lack of response or follow-up from the authorities, which made their efforts feel undervalued.

Other barriers included limited access to reporting tools. Although reporting mechanisms such as the Yellow Card and Med Safety App were available, it was widely reported that pharmacists especially those in rural areas were either unaware of these tools or lacked the digital resources to use them effectively (NAFDAC, 2023). Paper-based forms were often unavailable, and many pharmacists were unclear about submission procedures.

Finally, researchers drew attention to institutional and policy-related barriers. It was emphasized that community pharmacists often operated without clear institutional support or regulatory mandates compelling them to report ADRs. Akwagyiram (2011) noted that some pharmacy owners even discouraged ADR reporting out of concern for legal implications or damage to business reputation. The absence of incentives, recognition, or penalties meant that ADR reporting remained a low priority. In light of these findings, it was concluded that underreporting among community pharmacists was a multifactorial problem. Authors and experts alike called for comprehensive interventions addressing knowledge gaps, workflow integration, motivational incentives, and systemic support. Regulatory agencies such as NAFDAC were urged to scale up pharmacist training, improve access to user-friendly reporting platforms, and build a stronger feedback loop between reporters and the authorities.

### 1.3.4: STRATEGIES TO IMPROVE ADVERSE DRUG REACTION REPORTING BY COMMUNITY PHARMACISTS

As the most approachable medical professionals, community pharmacists play a vital role in the healthcare system. They are in a unique position to notice and report adverse drug reactions (ADRs) because of their frequent patient interactions, particularly in outpatient and retail settings. However, in many nations, including Nigeria, community pharmacists' ADR reporting rates are still below ideal despite their strategic role. To close this gap and improve community pharmacists' contribution to pharmacovigilance, a number of focused strategies have been identified such as follows:

1. Capacity building and continuous education: ADR reporting rates have significantly increased as a result of training programs that emphasize the fundamentals and applications of pharmacovigilance (Amesu, 2018). Identification of ADRs, the value of spontaneous reporting, and the use of readily available reporting tools, like the Yellow Card Scheme or mobile reporting apps, should all be covered in these trainings. Pharmacists can also become more confident in evaluating and reporting suspected adverse drug reactions by incorporating real-life case studies and simulations into training sessions (Lopez-Gonzalez et al., 2009). Incorporating pharmacovigilance into undergraduate pharmacy curricula, in addition to standalone trainings, guarantees that aspiring pharmacists have the knowledge and abilities they need right from the start of their careers. According to Olsson et al. (2010), this strategy not only develops long-term competency but also cultivates a culture in which ADR reporting is accepted as the standard rather than an infrequent duty.

2. Simplifying the reporting procedure: If the system is easy to use, quick, and convenient, pharmacists are more likely to report adverse drug reactions. Great advancements in this area can

be seen in tools like the Med Safety App, which was created by the Uppsala Monitoring Center and the National Agency for Food and Drug Administration and Control (NAFDAC) in partnership with the World Health Organization (WHO). The app reduces time and effort barriers by enabling the rapid electronic submission of ADR reports and integrating it into pharmacists' daily workflow (NAFDAC, 2023).

3. Raising awareness about the importance of ADR reports: Pharmacists are more inclined to report ADR when they realize that even one report can help with more extensive public health initiatives like safety alerts, drug label modifications, or the discontinuation of dangerous drugs (Edwards and Aronson, 2000). Regular feedback systems can help to strengthen this sense of contribution. Regular newsletters or bulletins summarizing reported ADR trends, regulatory responses, and practical outcomes derived from pharmacist-led reports, for example, can be distributed by regulatory bodies or professional associations.

4. Providing incentives for reporting efforts: ADR reporting is largely a professional duty, but small rewards like certificates, recognition awards, or continuing professional development (CPD) credits can encourage pharmacists to make it a priority. These rewards raise the standing of pharmacovigilance in the industry while also recognizing individual efforts (Ampadu et al., 2016).

5. Institutional support and collaborative practices: Since community pharmacists frequently work alone, they might not have as much access to professional peer support or pharmacovigilance updates. Hence, creating local networks, like regional pharmacovigilance hubs or community pharmacy clusters, can encourage cooperation, information exchange, and group reporting. Professional associations like the Association of Community Pharmacists of

Nigeria (ACPN) and the Pharmaceutical Society of Nigeria (PSN) can also help standardize procedures and promote systemic changes.

6. Lastly, it is critical to close the gaps in infrastructure and technology, particularly in underserved and rural areas. Logistical obstacles to ADR documentation will be lessened by offering user support services, dependable reporting platforms, and internet access. To keep pharmacists involved in the reporting process, it's also vital to make sure they are informed about drug safety alerts and regulatory changes, regardless of where they work (WHO, 2020).

**1.4: GUIDELINES FOR REPORTING ADVERSE DRUG REACTIONS (ADRs)**

Effective pharmacovigilance depends on timely and accurate reporting of suspected adverse drug reactions (ADRs). A structured and inclusive approach is essential, particularly in Nigeria, where strengthening ADR reporting is a national priority (NAFDAC, 2023). The following outlines the standard procedures and practical guidance for healthcare professionals, especially community pharmacists, on how to report ADRs correctly and effectively.

1. Who Can Report ADRs?

ADR reporting is a shared responsibility across all levels of healthcare. According to NAFDAC (2023), the following groups are authorized to submit reports:

- Pharmacists

- Physicians

- Nurses

- Dentists

- Patients or caregivers

These reporters often have the first contact with patients and are in a position to detect abnormal drug responses. Encouraging a broad base of reporters ensures a more complete surveillance system (WHO, 2020).

2. What Should Be Reported?

Healthcare professionals are encouraged to report any suspected ADR, especially when the following apply (WHO, 2020; NAFDAC, 2023):

- Serious or life-threatening reactions

- Unexpected or rare side effects

- Reactions involving newly marketed drugs or vaccines

- ADRs causing hospitalization, disability, or death

- Reactions in special populations (e.g., children, pregnant women, elderly)

- Suspected medication errors, drug interactions, overdose, or product quality issues

Note: Uncertainty about causality should not deter reporting. Accumulated data from multiple reports can reveal patterns not immediately obvious in individual cases (Edwards et al., 2012).

3. When to Report: The ideal time to report is immediately after an ADR is suspected. Prompt reporting allows regulators to take quicker action in identifying safety signals and protecting public health (UMC, 2022).

4. How to Report ADRs in Nigeria: There are several accessible reporting channels such as follows:

- Yellow Card System: Paper-based forms available in hospitals and pharmacies

- Online reporting portals: Found on NAFDAC's official website

- Med Safety App: A mobile reporting tool developed by NAFDAC in partnership with the WHO and UMC (NAFDAC, 2023)

- Hospital Pharmacovigilance Officers or Zonal NAFDAC Offices

Each report should follow a structured format to ensure completeness and utility. A standard report should include:

- Patient's age, sex, and anonymized ID

- Description of the adverse reaction

- Name of the suspected drug(s), dosage, and route of administration

- List of other concurrently administered medications

- Outcome of the reaction (e.g., recovered, ongoing, fatal)

- Reporter's details (kept confidential)

5. Legal Protection for Reporters: Healthcare providers who submit ADR reports in good faith are not legally liable, even if the suspected medication is later cleared of causing the reaction. This principle aims to eliminate fear of litigation or professional repercussions and encourage honest reporting (Edwards and Aronson, 2000; Olsson et al., 2010).

6. Support Tools and Digital Innovation: The Med Safety App simplifies the reporting process and addresses earlier challenges such as limited internet access, complex paperwork, or lack of forms. It also allows offline reporting, provides updates on submitted cases, and ensures data privacy (NAFDAC, 2023; UMC, 2022).

7. Reporting Quality: Timeliness and Completeness

Regulatory bodies rely on complete, high-quality data to detect and act on safety issues. Incomplete or delayed reports may allow harmful drugs to remain in circulation longer than necessary, endangering patients. Timeliness and thoroughness are therefore essential to an effective pharmacovigilance system (WHO, 2020). For pharmacovigilance efforts to be successful, healthcare professionals must be actively involved in ADR reporting. Understanding who can report, what should be reported, how and when to report, and the legal and institutional support in place are key. Digital tools and education continue to play an important role in strengthening the pharmacovigilance system in Nigeria and beyond.

## 1.5: SYSTEM OF OPERATIONS (SOPS) FOR PREVENTING ADVERSE DRUG REACTIONS (ADRs)

1. Obtain full medical/medication history of patients.

2. Avoid unnecessary medication use and encourage non-pharmaceutical approaches when possible.

3. Be mindful of drug-drug, drug-food, and drug-disease interactions.

4. Adjust doses of drugs in special cases like in children, elderly, pregnancy, and other disease conditions like renal/hepatic impairments.

5. Beware of cautions/precautions necessary in the use of some drugs.

6. Ask your patients to return to the pharmacy if they encounter any problems with their medications.

7. Always look out for and report all ADRs in your patients - fill the yellow form in such cases or use the Medsafety mobile app.

## 1.6: STATEMENT OF PROBLEM

In Nigeria, the situation with adverse drug reactions (ADRs) and their reporting is particularly bad, such that a significant percentage of patients experience ADRs during treatment (Oladapo et al., 2020). Community pharmacists should play a vital role in identifying and reporting adverse drug reactions as front-line healthcare professionals. However, little is known about their knowledge, attitudes, and ADR reporting practices. (Afolabi et al. 2021)

The problem of inadequate ADR reporting among community pharmacists in Nigeria is multifaceted. Studies have shown that reporting rates are low, with many ADRs going unreported (Hazell & Shakir, 2006). For instance, a study by Afolabi et al. (2021) found that only 27% of community pharmacists in Nigeria reported ADRs to the relevant authorities. This lack of reporting may be attributed to various factors, including limited knowledge and training on ADR reporting, inadequate feedback, and insufficient resources and infrastructure to support reporting.

The consequences of inadequate ADR reporting are severe, resulting in increased morbidity and mortality, prolonged hospital stays, and increased healthcare costs (Lazarou et al., 1998). Furthermore, delayed or inadequate treatment of ADRs can lead to poor patient outcomes and

decreased quality of life. Therefore, it is essential to improve the knowledge, attitudes, and practices of community pharmacists towards ADR reporting.

To address this issue, targeted training programs, feedback on ADR reporting, and adequate resources and infrastructure to support reporting are necessary. This insight into the knowledge, attitudes, and practices of community pharmacists in Benin City, Nigeria, regarding ADR reporting is crucial for developing effective solutions. Through this investigation, we seek to uncover the underlying challenges and obstacles that hinder ADR reporting, ultimately informing the creation of tailored interventions that boost reporting rates and prioritize patient safety.

### 1.7: JUSTIFICATION OF THE STUDY

A study carried out in Lagos State by Usifoh et al. (2018) sought to assess the knowledge, attitudes, and practices of community pharmacists regarding ADR reporting. The findings showed that although about 62.7% of respondents were familiar with ADR reporting, only 27% had ever reported a serious reaction. Interestingly, 78.4% of them had encountered such reactions in the months leading up to the study. Several reasons were offered for the low level of reporting. These included uncertainty about whether the drug truly caused the reaction (52%), lack of clarity on which reactions to report (38.2%), unavailability of ADR forms (33.8%), and limited knowledge of reporting procedures (30.4%). The study concluded that underreporting was largely due to a lack of formal training and insufficient knowledge in pharmacovigilance.

A similar study by Bello and Atunwa (2018) was conducted among community pharmacists in Ilorin. It found that over half of the pharmacists surveyed (58%) had never reported an ADR. Only a small portion would consider reporting if they were completely sure that the medicine was responsible for the reaction. One of the major setbacks reported was the unavailability of the

Yellow ADR reporting forms. In addition, almost half of the participants (47%) had not received any formal training in pharmacovigilance, although a large majority (84%) expressed willingness to undergo training. The study concluded that although moderate levels of awareness existed, the gaps in practice were still significant and highlighted the urgent need for appropriate training and resources to support pharmacists in fulfilling their reporting roles.

In another part of Lagos, a study by Olugbake et al. (2023) further confirmed these trends. Out of the pharmacists who participated in the research, over 96% believed that ADR reporting was essential to pharmacovigilance, indicating a generally positive attitude. However, the number who had actually reported ADRs was just 24.2%, pointing again to a disconnect between awareness and practice. The researchers observed that despite good levels of awareness, many community pharmacists still lacked the necessary support and routine procedures to report ADRs effectively. The study emphasized the need for continuous training and the integration of ADR reporting systems into daily practice in pharmacies.

The situation in Ogun State was equally explored by Adebukola et al. (2024), who conducted a study involving community pharmacists in various urban areas. 78.1% of the participants understood what pharmacovigilance was, and 73.1% were knowledgeable about how to report ADRs. Notably, 99.6% of the respondents agreed that ADR reporting was important. Yet, practical barriers remained as 51.9% of respondents indicated the lack of time as a key reason for not reporting, while 96.3% believed that having easier access to reporting forms would improve their reporting rates. The study concluded that although awareness and attitude were commendable, the practical issues around time, access, and workflow continued to limit reporting.

In an intervention-based study conducted by Osagie et al. (2023) to assess the effects of health education on the knowledge, attitude and practice of ADR reporting among community pharmacists in Anambra State, the study compared two groups, one that received targeted health education on ADR reporting and one that did not. Before the intervention, only 52% of the pharmacists in the study group showed good knowledge of ADR reporting. This figure rose to 95.3% after the training, while the control group showed no improvement. Reporting practices also improved in the intervention group, from 26.7% before the training to significantly higher engagement afterward. The researchers concluded that structured educational programs could not only improve knowledge but also translate into better practice, especially when adapted to local community pharmacy settings.

Although the above studies have been conducted in various geographical locations, no study has been done to assess the knowledge, attitudes and practice of adverse drug reaction in Benin city. Hence, this study is vital as it seeks to build on this body of evidence by examining how these same issues apply locally. Furthermore, findings from this study will help inform policymakers and regulatory agencies on the need to develop tailored training programs and support systems to enhance the reporting of adverse drug reactions, ultimately improving the quality of pharmacovigilance in community pharmacy settings.

### 1.8: AIM OF THE STUDY

The aim of this study is to assess the knowledge, attitude, and practice (KAP) of community pharmacists in Benin City regarding adverse drug reaction (ADR) reporting.

## 1.9: OBJECTIVES OF THE STUDY

1. Assess the awareness of community pharmacists towards pharmacovigilance and adverse drug reaction (ADR) reporting practices.

2. Assess the knowledge of community pharmacists about drug-induced diseases (iatrogenic diseases).

3. Evaluate the attitudes of community pharmacists towards ADR reporting.

4. Investigate the practice of ADR reporting among community pharmacists.

5. Identify the challenges or barriers to effective ADR reporting among community pharmacists.

# CHAPTER TWO

# METHODS

## 2.1: STUDY SETTING

The study setting for the study encompassed various registered community pharmacies located in urban and suburban areas across Benin City.

## 2.2: STUDY DESIGN

A cross-sectional study design was conducted to assess the knowledge, attitude and practice of community pharmacists on adverse drug reactions reporting. Following ethical approval and informed consent from the study participants, a structured questionnaire was used to collect the required information from each participant.

## 2.3: STUDY POPULATION

The study population for this study focused on licensed community pharmacists practicing in urban and suburban areas of Benin City.

### 2.3.1: INCLUSION CRITERIA

All registered pharmacists practicing in a community pharmacy setting within Benin City.

Pharmacists who were present and available during data collection and gave informed consent.

### 2.3.2: EXCLUSION CRITERIA

Pharmacists not practicing in a community pharmacy setting.

Non-pharmacist staff such as pharmacy technicians or attendants.

Pharmacists who declined consent or were unavailable at the time of data collection.

## 2.4: SAMPLING TECHNIQUE AND SAMPLE SIZE

A convenient sampling technique was employed in this study. Community pharmacists practising within Benin City were approached at their pharmacies during working hours and invited to participate voluntarily. Community pharmacists who were also present at the monthly general meeting of the ACPN, Edo branch were also invited to participate voluntarily. Pharmacists who were available and willing to participate at the time of visit were recruited until the desired sample size was reached. This approach was selected due to the accessibility of pharmacists within their premises and the feasibility of collecting data during their routine operations. The sample size for this study was calculated using the Slovin formula from the sample population as stated below:

$n = N/1+Ne^2$

Population of community pharmacists in Edo State according to the Association of Community Pharmacists of Nigeria (ACPN) database 2025 is within the range of 400-500 community pharmacists. However, recent statistics showed specifically that there were 286 community pharmacists in Benin City as of May 5th, 2025.

Where;

N= Total population

n= sample size

E= Error margin at specified confidence level, using confidence level of 95% and percentage error of 5% (0.05)

$n= 286/1 + 286 \times (0.05)^2$

n= 286/ (1 + 0.715)

n= 286/1.715

n= 167

In order to account for loss due to attrition, 10% (17) of the sample size was added making the sample size 184.

Therefore, a total of 184 questionnaires were distributed to community pharmacists.

**2.5: STUDY INSTRUMENT**

The data collection instrument used for this study was a 52 item structured self-administered questionnaire as adapted from (Tihani A, Mohannad O, Ameerah HJ, Eman H, Aya B 2025) modified to suit the current study and divided into five sections (A, B, C, D and E). Section A comprised of the social demographics of the participants which included Age, Sex, Educational level, and Years of practice. Section B comprised of 15 questions that assessed community pharmacists' awareness of pharmacovigilance and adverse drug reaction reporting. The response choice for the awareness was “yes” and “no”. Section C comprised of 10 questions that assessed community pharmacists' knowledge about drug-induced diseases and the response choice was "yes", "no" and "I don't know". Section D comprised of 10 questions that assessed community pharmacists attitude towards ADR reporting and the response choice was a five-point Likert scale – strongly agree, agree, neutral, disagree, strongly disagree. Section E comprised of 12 questions that assessed the practice of ADR reporting among community pharmacists. The response choice was a three-point Likert scale – always, sometimes and never.

## 2.6: VALIDITY OF THE STUDY INSTRUMENT

A pilot test with 20 community pharmacists was conducted to ensure clarity, reliability and content validity of the research instrument. The questionnaire's reliability test revealed an acceptable level of internal consistency after calculating Cronbach's Alpha coefficient determined to be 0.772.

## 2.7: DATA COLLECTION

A self-administered, structured questionnaire based on the study objectives was utilized as the primary instrument for data collection. Paper-based questionnaires were distributed to community pharmacists in their different pharmacies and also to community pharmacists present during the monthly general meeting of the Association of Community Pharmacists (ACPN) Edo branch as approved by the ACPN Chairman. Electronic-based questionnaires were also sent to the Young Pharmacists Group (YPG) Edo branch as approved by the YPG Chairman. Since a convenience sampling technique was used, participation depended on the pharmacists' availability and willingness at the time of data collection.

## 2.8: DATA ANALYSIS

All data collected during the study were first coded using letters and numbers. The coded letters and numbers were then entered into a statistical software program called SPSS version 29. This software was used to carry out descriptive and inferential analysis of the collated data. Chi-square test was used for the inferential statistics to examine associations between the study variables.

## 2.9: ETHICAL CONSIDERATION

This study was conducted with strict adherence to ethical guidelines to ensure the integrity of the research. Before data collection, ethical approval was obtained from the Ethic committee, Faculty of Pharmacy, University of Benin. All participating pharmacists were provided an informed consent, guaranteeing the right to privacy, confidentiality and the ability to withdraw from the study at any point without penalty. To safeguard participant anonymity, all data were securely stored and made anonymous. Participation was voluntary, and only pharmacists who provided informed consent were included based on convenience sampling.

## CHAPTER THREE

## RESULT

### 3.1: Demographic data

A total of 184 pharmacists participated, with a male predominance (65.4%) compared to females (34.6%). Almost half of the participants were aged 31–40 years (47.6%), followed by 27% younger than 30 years. In terms of education, most held a Pharm.D (65.4%), while 28.6% had Master's degrees. Regarding years of practice, 36.8% had 3–5 years' experience and 21.6% had 6–10 years. Only 8.1% had more than 30 years of practice experience.

**Table 3.1: Demographic data**

| categories | Frequency | Percent(%) |
|---|---|---|
| Gender | | |
| Male | 121 | 65.4 |
| female | 64 | 34.6 |
| Age | | |
| less than 30 | 50 | 27.0 |
| 31 - 40 | 88 | 47.6 |
| 41 - 50 | 23 | 12.4 |
| 51 - 60 | 12 | 6.5 |
| above 60 | 12 | 6.5 |

| | | |
|---|---|---|
| Educational level | | |
| B. Pharm | 2 | 1.1 |
| Pharm. D | 121 | 65.4 |
| Masters | 53 | 28.6 |
| PhD | 1 | .5 |
| others | 8 | 4.3 |
| years of practice | | |
| 1-2 years | 35 | 18.9 |
| 3-5 years | 68 | 36.8 |
| 6-10 years | 40 | 21.6 |
| 11-15 years | 16 | 8.6 |
| 16-20 year | 5 | 2.7 |
| 21-25 year | 2 | 1.1 |
| 25- 30 year | 4 | 2.2 |
| Above 30 years | 15 | 8.1 |

### 3.2: Descriptive analysis on awareness of Community Pharmacists about Pharmacovigilance and ADR Reporting

Overall, almost all respondents 98.9% acknowledged that adverse drug reactions (ADRs) should be reported by the community pharmacists and recognized the importance of such reporting for patient safety. 61.6% of the respondents noted that there were possible barriers or challenges that community pharmacists face in reporting ADRs while almost all the respondents 97.3% acknowledged that ADR reporting should be improved.

**Table 3.2: Descriptive analysis on awareness of Community Pharmacists about Pharmacovigilance and ADR Reporting**

| Categories | Frequency | Percent(%) |
|---|---|---|
| Monitoring of ADR by the community pharmacist | | |
| no | 3 | 1.6 |
| yes | 182 | 98.4 |
| ADRs should be reported by the community pharmacist | | |
| no | 2 | 1.1 |
| yes | 183 | 98.9 |
| importance of ADR reporting in patient safety | | |
| no | 2 | 1.1 |
| yes | 183 | 98.9 |

| | | |
|---|---|---|
| role of community pharmacists in ADR reporting | | |
| no | 29 | 15.7 |
| yes | 156 | 84.3 |
| training on ADR reporting | | |
| no | 57 | 30.8 |
| yes | 128 | 69.2 |
| Knownledge on guidelines for ADR reporting in Nigeria | | |
| no | 17 | 9.2 |
| yes | 168 | 90.8 |
| potential consequences of not reporting ADRs | | |
| no | 29 | 15.7 |
| yes | 152 | 82.2 |
| understanding of Pharmacovigilance | | |
| I'm not sure but I could choose option B | 8 | 4.3 |
| I'm not sure but I could choose option A | 18 | 9.7 |
| Detection, assessment, understanding and prevention of ADR | 28 | 15.1 |
| The reporting of ADR | 131 | 70.8 |

| | | |
|---|---|---|
| pharmacovigilance centers in Nigeria | | |
| no | 81 | 43.8 |
| yes | 104 | 56.2 |
| Who is responsible for reporting ADRs | | |
| Any healthcare professional | 143 | 77.3 |
| Both patients and healthcare professionals | 40 | 21.6 |
| barriers or challenges to ADR reporting | | |
| no | 64 | 34.6 |
| yes | 114 | 61.6 |
| possible barriers to ADR reporting | | |
| Uncertainty about causality | 58 | 13.7 |
| Apathy to ADR reporting | 33 | 7.8 |
| Not sure of the ADR to report | 15 | 3.5 |
| Unavailability of ADR reporting forms | 114 | 27 |
| Lack of time and workload | 52 | 12.3 |
| Complexity of the ADR reporting form | 37 | 8.7 |
| Fear of having caused an ADR | 12 | 2.8 |

| | | |
|---|---|---|
| No rewards for reporting a suspected ADR | 41 | 9.7 |
| Lack of knowledge about ADR reporting | 27 | 6.4 |
| Not being clear on what to do after filling the form | 34 | 8.0 |
| improving ADR reporting | | |
| no | 3 | 1.6 |
| yes | 180 | 97.3 |
| How do you think ADR reporting can be improved | | |
| Inclusion of ADR reporting in healthcare professional curriculum | 153 | 21.9 |
| Regular training on ADR reporting | 112 | 16.0 |
| Strengthening regulatory policies | 95 | 13.6 |
| Regular communication and feedback | 111 | 15.9 |
| Improved access to ADR reporting forms and online platforms | 123 | 17.6 |
| Increased funding for pharmacovigilance activities | 105 | 15.0 |

**3.3: Descriptive Analysis on knowledge of Drug-induced diseases**

The mean knowledge score was 13.5 ± 2.91 out of 20. Most pharmacists correctly identified gastritis from NSAIDs (91.9%) and obesity from risperidone (74.1%). Knowledge was weaker for hypotension from ceftriaxone (32.4%) and Parkinsonism from cinnarizine (43.2%). Moderate

awareness was noted for osteoporosis from methotrexate (59.5%) and hyponatremia from carbamazepine (48.1%). Overall, pharmacists demonstrated fair knowledge, though gaps exist in less common ADRs**.**

**Table 3.3: Descriptive Analysis on knowledge of Drug-induced disease**

| | No | I don't know | Yes |
|---|---|---|---|
| Gastritis can be induced by taking nonsteroidal anti-inflammatory drugs | 13(7.0%) | 2(1.1%) | 170(91.9%) |
| Paralytic ileus can be induced by taking loperamide | 14(7.6%) | 39(21.1%) | 130(70.3%) |
| Hypotension can be induced by taking ceftriaxone injection | 73(39.5%) | 52(28.1%) | 60(32.4%) |
| Hyponatremia leading to ischemic heart disease can be induced by taking carbamazepine | 31(16.8%) | 65(35.1%) | 89(48.1%) |
| Parkinsonism can be induced by taking cinnarizine | 37(20.0%) | 68(36.8%) | 80(43.2%) |
| Obesity can be induced by taking risperidone | 19(10.3%) | 29(15.7%) | 137(74.1%) |
| Dyslipidaemia can be induced by taking steroids (like | 16(8.6%) | 33(17.8%) | 136(73.5%) |

| | | | |
|---|---|---|---|
| estrogen & androgens) | | | |
| Rhinitis can be induced by taking beta-blockers | 32(17.3%) | 56(30.3%) | 95(51.4%) |
| Pruritus can be induced by taking ACEI's | 36(19.5%) | 48(25.9%) | 97(52.4%) |
| Osteoporosis can be induced by taking methotrexate | 29(15.7%) | 42(22.7%) | 110(59.5%) |

**3.4: Descriptive Analysis on pharmacist attitude towards ADR reporting**

The mean attitude score was 3.83 ± 0.42, showing generally positive attitudes. A large majority agreed that ADR reporting improves safety (87%) and that pharmacists have a responsibility to report ADRs (94.1%). Confidence in identifying ADRs was high (84.9% agreed/strongly agreed). Some concerns were expressed about time burden (37.8%) and legal implications (36.2%). Nearly all respondents (96.7%) believed ADR reporting could be improved in community practice.

**Table 3.4: Descriptive Analysis on pharmacist attitude towards ADR reporting**

| | **Strongly agree** | **Agree** | **Neutral** | **Disagree** | **Strongly disagree** |
|---|---|---|---|---|---|
| ADR reporting is very important; it improves medication safety and | 161(87.0%) | 20(10.8) | 2(1.1%) | 0(0%) | 2(1.1%) |

| | | | | | |
|---|---|---|---|---|---|
| patient outcomes | | | | | |
| I'm satisfied that I received sufficient education/training about drug-induced diseases, and I have enough knowledge about drug-induced diseases. | 39(21.1%) | 68(36.8%) | 56(30.3%) | 20(10.8%) | 2(1.1%) |
| As a community pharmacist, I have a responsibility to report ADR to NAFDAC. | 110(59.5%) | 64(34.6%) | 8(4.3%) | 3(1.6%) | 0(0%) |
| I feel confident in my ability to identify ADRs. | 63(34.1%) | 94(50.8%) | 23(12.4%) | 3(1.6%) | 2(1.1%) |
| I am motivated to report adverse drug reactions in my practice | 51(27.6%) | 88(47.6%) | 35(18.9%) | 11(5.9%) | 0(0%) |
| I am uncertain about recommending stopping the drug that I absolutely know it's association with | 16(8.6%) | 25(13.5%) | 48(25.9%) | 54(29.2%) | 42(22.7%) |

| | | | | | |
|---|---|---|---|---|---|
| the reported problem by the patient. | | | | | |
| ADR reporting is time consuming and burdensome. | 18(9.7%) | 52(28.1%) | 43(23.2%) | 58(31.4%) | 14(7.6%) |
| I am concerned about potential legal implications of reporting ADRs | 17(9.2%) | 50(27.0%) | 57(30.8%) | 44(23.8%) | 15(8.1%) |
| As a community pharmacist, I should only be required to consult the prescribing physician when a patient reports any problem associated to certain drugs | 23(12.4%) | 41(22.2%) | 23(12.4%) | 65(35.1%) | 31(16.8%) |
| i think adverse drug reaction reporting could be improved community practice setting. | 119(64.3%) | 60(32.4%) | 4(2.2%) | 0 | 2(1.1%) |

### 3.5: Descriptive Analysis on pharmacist practice of ADR reporting

The mean practice score was 13.1 ± 4.13 out of 24, indicating moderate practice. Most respondents reported always reviewing patients' medication lists (63.2%) and asking about symptoms (83.2%). Only a few consistently counseled on ADRs (38.4% always) or reported ADRs in practice (17.3% always). Recording ADRs in medical records was uncommon (56.2% never). Participation in training and use of electronic systems were also limited.

**Table 3.5: Descriptive Analysis on pharmacist practice of ADR reporting**

| | Alway | Sometimes | Never |
|---|---|---|---|
| Do you review patient's medication list | 117(63.2) | 65(35.1) | 2(1.1) |
| If patients tell you about symptoms which occur with them, do you ask them about their medication list. | 154(83.2) | 31(16.8) | 0 |
| Do you counsel the patients on potential ADRs when dispensing a new drug | 71(38.4) | 105(56.8) | 5(2.7) |
| How often do you report ADR in your community practice | 32(17.3) | 96(51.9) | 55(29.7) |
| During your professional career, do you record the reported ADRs from patients on Patient's medical records | 16(8.6) | 65(35.1) | 104(56.2) |
| | 66(35.7) | 85(45.9) | 32(17.3 |

| | | | |
|---|---|---|---|
| When you identify a serious ADR, how often do you n healthcare provider | | | ) |
| When encountering a patient with known ADR, how often do you adjust their medication regimen accordingly or withdraw the medication. | 83(44.9) | 86(46.5) | 16(8.6) |
| How often do you use electronic reporting systems for ADR reporting | 59(31.9) | 59(31.9) | 20(10.8 ) |
| Do you discuss ADR reporting with your colleagues | 66(35.7) | 97(52.4) | 22(11.9 ) |
| Do you participate in training or educational programs on ADR reporting | 21(11.4) | 103(55.7 ) | 61(33.0 ) |

**3.6: Association between knowledge level and pharmacist demographics**

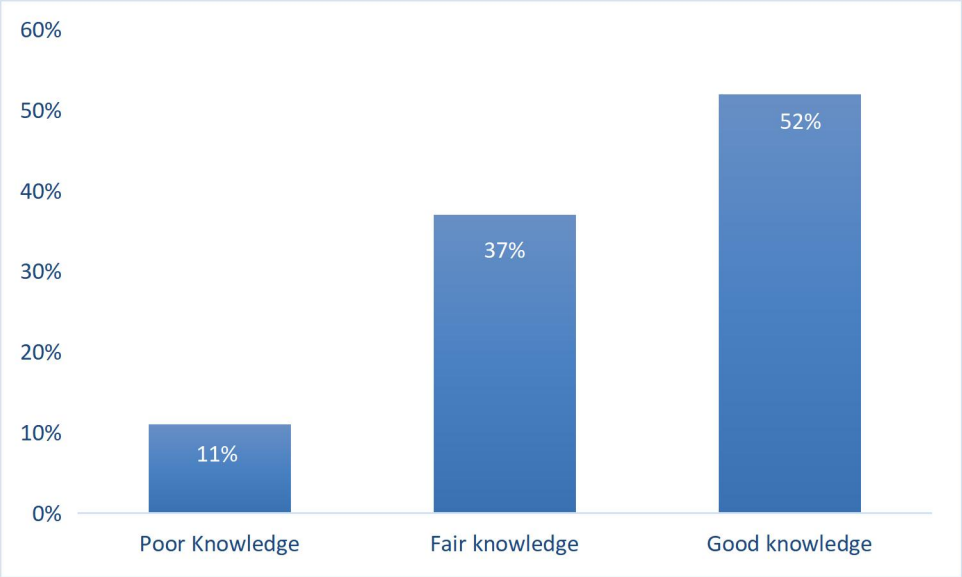
Chi-square analysis showed a significant association between knowledge and years of practice ($p < 0.001$), with pharmacists in the 3–10 year range demonstrating better knowledge. No significant association was found with educational level ($p = 0.060$).

**Table 3.6: Association between knowledge level and pharmacist demographics**

| | high | fair | poor | Sig. |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| | | | | level |
| Educational level | | | | .060 |
| B.Pharm | 0 | 2 | 0 | |
| Pharm.D | 58 | 53 | 10 | |
| Masters | 34 | 11 | 8 | |
| PhD | 1 | 0 | 0 | |
| years of practice | | | | .000 |
| 1-2 years | 20 | 11 | 4 | |
| 3-5 years | 32 | 32 | 4 | |
| 6-10 years | 26 | 13 | 1 | |
| 11-15 years | 10 | 4 | 2 | |
| 16-20 year | 5 | 0 | 0 | |
| 21-25 year | 0 | 0 | 2 | |
| 25- 30 year | 0 | 2 | 2 | |
| Above 30 years | 4 | 6 | 5 | |

**Assessment of the knowledge of community pharmacists about Iatrogenic diseases.**




**Mean knowledge score = 13.5±2.91**

***Fig 1* knowledge level**

### 3.7: Association between attitude level and pharmacist demographics

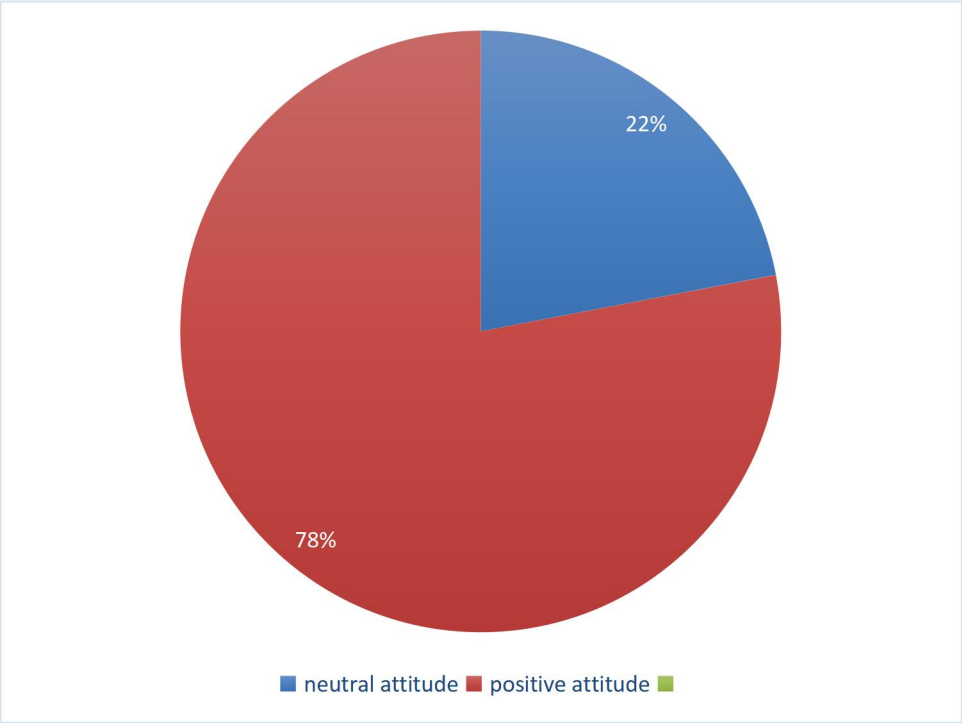
Overall, positive attitudes predominated across age groups (e.g., 31–40 years: 73 positive vs 15 neutral; <30 years: 36 positive vs 14 neutral). Chi-square analysis showed a significant association between attitude level and age ($\chi^2 = 11.301$, $p = 0.023$) and years of practice ($\chi^2 = 26.985$, $p < 0.001$), with the younger and less-experienced pharmacists showing more positive attitudes. Educational level was not significantly associated with attitude ($p = 0.745$).

**Table 3.7: Association between attitude level and pharmacist demographics**

| | positive | neutral | negative | Sig. level |
|---|---|---|---|---|
| Age | | | | .023 |
| less than 30 | 36 | 14 | 0 | |
| 31 - 40 | 73 | 15 | 0 | |
| 41 - 50 | 18 | 5 | 0 | |
| 51 - 60 | 12 | 6 | 0 | |
| above 60 | 12 | 0 | 0 | |
| Educational level | | | | .745 |
| B.Pharm | 2 | 0 | | |
| Pharm.D | 92 | 29 | | |
| Masters | 44 | 9 | | |
| PhD | 1 | 0 | | |
| other | 6 | 2 | | |
| years of practice | | | | .000 |
| 1-2 years | 26 | 9 | | |
| 3-5 years | 54 | 14 | | |
| 6-10 years | 37 | 3 | | |
| 11-15 years | 8 | 8 | | |
| 16-20 year | 3 | 2 | | |

| | | |
|---|---|---|
| 21-25 year | 0 | 2 |
| 25- 30 year | 2 | 2 |
| Above 30 years | 15 | 0 |

**Evaluation of the attitudes of community pharmacists towards ADR reporting.**




**Mean attitude level = 3.83±0.42**

***Fig 2_*** **Attitude level**

### 3.8: Association between practice level and pharmacist demographics

Chi square analysis showed a significant association between gender and practice level (p = 0.031) with male respondents having 12 good practice scores. No significant associations were

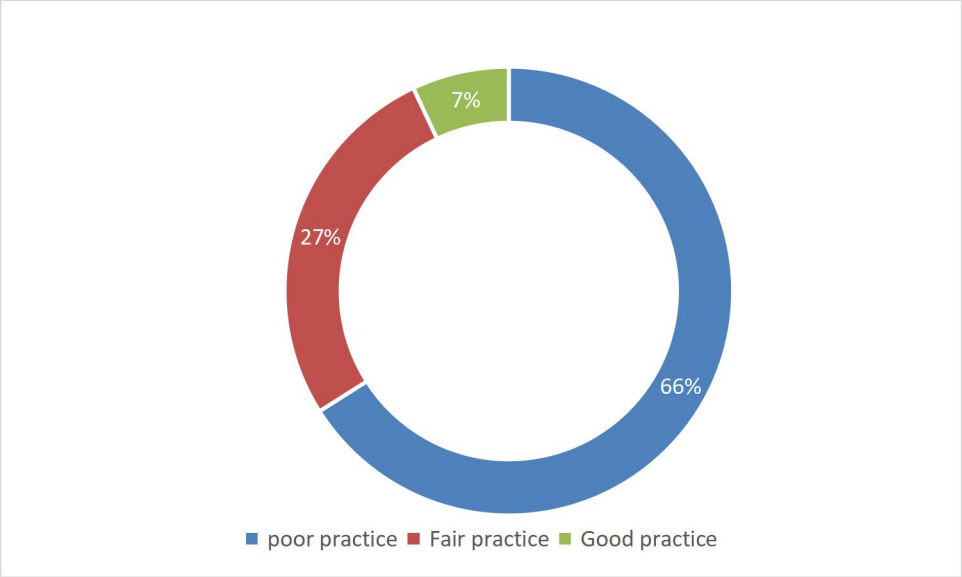
observed between age (p = 0.384), educational level (p = 0.116), and years of practice (p = 0.340).

**Table 3.8: Association between practice level and pharmacist demographics**

| Variable | poor practice | fair practice | good practice | Sig. Level |
|---|---|---|---|---|
| Gender | | | | **.031** |
| Male | **71** | **32** | **12** | |
| female | **42** | **14** | **0** | |
| Age | | | | **.384** |
| less than 30 | **28** | **15** | **3** | |
| 31 - 40 | **53** | **21** | **8** | |
| 41 - 50 | **16** | **6** | **1** | |
| 51 - 60 | **10** | **0** | **0** | |
| above 60 | **6** | **4** | **0** | |
| Educational level | | | | **.116** |
| B. Pharm | **2** | **0** | **0** | |
| Pharm. D | **76** | **28** | **5** | |
| Masters | **29** | **17** | **5** | |
| PhD | **6** | **0** | **2** | |
| years of practice | | | | **.340** |
| 1-2 years | **19** | **11** | **1** | |

| | | | |
|---|---|---|---|
| 3-5 years | **40** | **18** | **6** |
| 6-10 years | **27** | **7** | **4** |
| 11-15 years | **12** | **4** | **0** |
| 16-20 year | **4** | **0** | **1** |
| 21-25 year | **0** | **2** | **0** |
| 25- 30 year | **2** | **0** | **0** |
| Above 30 years | **9** | **4** | **0** |

**Assessment of the practice of ADR reporting among community pharmacists.**




**Mean practice score = 13.1±4.13**

***Fig 3_*** **Practice level**

### 3.9: Challenges or barriers to ADR reporting among community pharmacists.

The top five reported barriers were unavailability of ADR forms (27%), uncertainty about causality (13.7%), lack of time/workload (12.3%), no rewards for reporting (9.7%), and complexity of the reporting form (8.7%). Other barriers such as apathy, fear of implication, and lack of knowledge were reported less frequently. These findings highlight that both structural challenges and motivational factors hinder effective ADR reporting among community pharmacists.

**Table 3.9: Top five barriers to ADR reporting**

| Challenges or barriers | Occurrence |
|---|---|
| Unavailability of ADR reporting forms | 27% |
| Uncertainty about causality | 13.7% |
| Lack of time and workload | 12.3% |
| No rewards for reporting a suspected ADR | 9.7% |
| Complexity of the ADR reporting form | 8.7% |

# CHAPTER FOUR

## DISCUSSION

The demographic data showed that most participants were young to middle-aged adults, predominantly between 31 and 40 years, 88(48%) and largely male 121(65%). This age range typically represents the most active segment of the pharmacy workforce in Nigeria (Adisa et al., 2019). The majority of the respondents held a Pharm.D degree, which shows the growing shift from the Bachelor of Pharmacy (B.Pharm) to the more clinically oriented Doctor of Pharmacy programme. Interestingly, most respondents had between 3 and 10 years of professional experience (59%), which explains the relatively good familiarity with pharmacovigilance concepts observed in this study, since recent graduates are often more exposed to updated curricula emphasizing patient safety and ADR reporting (Oshikoya et al., 2021).

The mean knowledge score was (13.5 ± 2.91) out of 20. This suggested a fair knowledge of ADRs and drug-induced diseases among community pharmacists. Pharmacists correctly recognized common ADRs such as gastritis caused by NSAIDs (91.9%) and obesity from risperidone (74.1%) but performed less well on less common or more complex reactions like hypotension from ceftriaxone (32.4%) and Parkinsonism from cinnarizine (43.2%). This pattern is consistent with findings from Onakpoya et al. (2020) and Adedeji et al. (2022), who also reported that pharmacists in southwestern Nigeria exhibited adequate understanding of common ADRs but less awareness of uncommon or delayed reactions. Such gaps indicate that while community pharmacists are adept at identifying predictable ADRs, ongoing continuing professional education remains essential to strengthen recognition of atypical or less familiar drug reactions.

Most respondents demonstrated a strong awareness of the importance of ADR reporting. Almost all the respondents (98.9%) acknowledged that ADRs should be reported by community pharmacists and recognized the importance of such reporting for patient safety. This finding aligns with previous studies conducted among community pharmacists in Lagos and Ilorin, which also reported high levels of awareness and positive attitudes towards ADR reporting (Usifoh et al., 2018; Bello & Atunwa, 2018). The high awareness observed in this study may reflect the growing influence of professional advocacy and the inclusion of pharmacovigilance topics in pharmacy education. This also aligns with similar studies conducted in Lagos (Ogunleye et al., 2020) and in Northern Nigeria (Umeokonkwo et al., 2018), where awareness levels exceeded 90%. However, despite this impressive awareness, only 17.3% of pharmacists reported ADRs consistently in practice. This gap between knowledge and practice underscores a long-standing problem in pharmacovigilance, the "know-do gap" where professionals possess knowledge but do not translate it into routine behavior (Gupta & Nayak, 2020).

The mean attitude score (3.83 ± 0.42) indicates a generally positive disposition toward ADR reporting. A large majority agreed that ADR reporting improves medication safety and patient outcomes, and that it is the pharmacist's responsibility to report suspected reactions. This positive disposition is consistent with findings from previous studies, such as Olugbake et al. (2023), which recorded a similar trend in Lagos. However, a positive attitude without corresponding practice highlights the influence of systemic and institutional barriers. Confidence in identifying ADRs was also high (84.9%), which suggests that pharmacists are not only knowledgeable but also motivated to contribute to pharmacovigilance efforts. These findings are consistent with those of Okezie et al. (2019) who reported that community pharmacists in Rivers State had high confidence in identifying ADRs, with 85.7% of respondents indicating they were

confident. The study also found that community pharmacists had good knowledge and positive attitudes towards ADR reporting.

The moderate mean practice score (13.1 ± 4.13) suggests that while pharmacists are aware and willing, their actual engagement in ADR reporting remains limited. The majority of respondents always reviewed patients' medication lists and inquired about symptoms, showing good clinical vigilance. However, less than 40% consistently counseled patients on ADRs, and just 17.3% always reported ADRs in practice. Similar practice deficiencies have been reported in studies from Ibadan (Adisa et al., 2019) and Port Harcourt (Oparah et al., 2021), where underreporting was linked to logistical constraints and inadequate feedback from regulatory authorities. The low frequency of ADR recording in medical records (56.2% never) and minimal use of electronic systems also suggest structural weaknesses within the current pharmacovigilance infrastructure.

A significant relationship was observed between knowledge and years of practice, with pharmacists who had between 3 and 10 years of experience showing better knowledge. This pattern might be attributed to recent exposure to updated pharmacovigilance concepts during professional training, whereas older practitioners may rely on outdated knowledge or limited contact with newer ADR monitoring initiatives. Likewise, attitude correlated significantly with age and years of practice ($p < 0.05$), with younger pharmacists displaying more positive attitudes toward ADR reporting. This finding mirrors reports by Osemene and Lamikanra (2012), who noted that younger pharmacists are more receptive to professional innovations and more willing to participate in reporting schemes compared to older counterparts who may be more skeptical of regulatory feedback mechanisms. The inferential analysis also revealed that certain demographic factors such as gender showed significant association with ADR reporting practice, while other variables like age, educational qualification, and years of practice did not show statistically

significant relationships. This implies that personal or contextual factors, rather than professional qualifications alone, may influence reporting behaviour. The result supports the observations of Afolabi et al. (2021), who found that socio-demographic factors did not consistently predict reporting practice among Nigerian pharmacists.

Regarding barriers, the most frequently cited obstacles were unavailability of ADR reporting forms (27%), uncertainty about causality (13.7%), and workload/time constraints (12.3%). These are consistent with previously reported barriers in Nigerian studies (Adisa et al., 2019; Umeokonkwo et al., 2018), as well as in other developing countries such as Ghana and India (Sabblah et al., 2020; Gupta & Nayak, 2020). The lack of feedback and incentives (9.7%) also discourages continued participation in ADR reporting systems. Interestingly, most respondents (97.3%) suggested that ADR reporting could be improved through inclusion of pharmacovigilance training in the pharmacy curriculum, regular workshops, and improved access to electronic reporting platforms. This reinforces the need for structured collaboration between NAFDAC, the Pharmacists Council of Nigeria, and pharmacy schools to institutionalize pharmacovigilance education and reporting culture.

The present findings collectively demonstrate that while community pharmacists in Benin City have commendable knowledge and positive attitudes toward ADR reporting, these do not automatically translate into robust reporting practices. This gap reflects systemic and organizational barriers rather than individual unwillingness. Effective solutions will therefore require institutional support, including simplified reporting systems, digital reporting tools, and periodic feedback to pharmacists who submit reports. Strengthening the interface between community pharmacies and NAFDAC's pharmacovigilance database would enhance reporting frequency and quality.

In all, this study corroborates the broader literature that community pharmacists remain underutilized in Nigeria's pharmacovigilance system despite their strategic position in patient care. Their accessibility to the public places them in an ideal position to detect and report ADRs early, thereby preventing escalation of adverse events. Encouragingly, the widespread willingness to engage, coupled with the recognition of ADR reporting as a professional duty, suggests that improvement is achievable if supportive policies, continuous education, and technological facilitation are sustained. The findings thus emphasize the need for government and regulatory agencies to strengthen pharmacovigilance capacity building and create a more enabling environment for community pharmacists to actively participate in ADR reporting, ensuring safer medication use and better therapeutic outcomes in Nigeria.

**Limitations of the study.**

This study utilised a convenience sampling technique, which may have introduced selection bias since only pharmacists who were available and willing to participate were included. As a result, the findings may not fully represent all community pharmacists in Benin City. Additionally, although inferential analyses were conducted to identify associations between study variables, the non-probability sampling method and cross-sectional design limit the generalisability and causal interpretation of these findings. The use of self-administered questionnaires may also have introduced response bias, as some participants might have provided socially desirable answers. Nonetheless, the results provide meaningful insight into the behavioural patterns and barriers affecting ADR reporting among community pharmacists in Benin City, offering a valuable evidence base for targeted interventions and training programs.

# CHAPTER FIVE

# CONCLUSION

This study assessed the knowledge, attitude, and practice of community pharmacists towards adverse drug reaction (ADR) reporting in Benin City, Edo State.

The findings revealed that community pharmacists possessed a good knowledge and demonstrated positive attitudes towards ADR reporting, yet their actual reporting practice remained suboptimal. While almost all respondents acknowledged the importance of ADR reporting and their professional responsibility in pharmacovigilance, only a small proportion consistently reported ADRs in their practice.

This study reinforces the critical role of community pharmacists in Nigeria's pharmacovigilance system. Bridging the gap between knowledge and practice will require sustained educational, regulatory, and technological interventions. When adequately empowered, community pharmacists can become indispensable agents in safeguarding the Nigerian public from preventable adverse drug reactions, thus promoting safer and more effective medication use nationwide.

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## APPENDIX

## QUESTIONNAIRE: ASSESSMENT OF COMMUNITY PHARMACISTS' KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVERSE DRUG REACTIONS REPORTING.

### SECTION A: DEMOGRAPHICS DATA

1. Gender: Male [ ] Female [ ]

2. Age: Less than 30 [ ] 30–40 [ ] 40–50 [ ] 50-60 [ ] Above 60 [ ]

3. Educational level: Diploma [ ] B Pharm. [ ] Pharm D. [ ] FPC Pharm. [ ] Masters [ ] PhD [ ]

4. Years of practice: 1-2 years [ ] 3-5 [ ] 6-10 [ ] 11-15 [ ] 16-20 [ ] 21-25 [ ] 25-30 [ ] Above 30 [ ]

### SECTION B: AWARENESS TOWARDS PHARMACOVIGILANCE AND ADR REPORTING PRACTICES

1. Do you think that adverse drug reactions could be monitored by the community pharmacist?

a. Yes [ ] b. No [ ]

2. Do you think that adverse drug reactions should be reported by the community pharmacist?

a. Yes [ ] b. No [ ]

3. Are you aware of the importance of adverse drug reaction reporting in patient safety?

a. Yes [ ] b. No [ ]

4. Have you ever received training on ADR reporting during your pharmacy education or professional development ? a. Yes [ ] b. No [ ]

5. Do you know about the guidelines for ADR reporting in Nigeria? a. Yes [ ] b. No [ ]

6. Are you aware of the role of community pharmacists in ADR reporting? a. Yes [ ] b. No [ ]

7. Do you know about potential consequences of not reporting ADRs? a. Yes [ ] b. No [ ]

8. What do you understand by Pharmacovigilance?

a. The reporting of adverse drug reactions [ ] b. Detection, assessment, understanding, and prevention of adverse drug reactions [ ] c. I'm not sure but I could choose option a [ ] d. I'm not sure but I could choose option b. [ ] e. I don't know [ ]

9. Are you aware of the pharmacovigilance centers in Nigeria? a. Yes [ ] b. No [ ]

10. Who is responsible for reporting adverse drug reactions ? a. Patient [ ] b. Any healthcare professional [ ] c. I don't know [ ]

11. Do you encounter any challenge or barrier to reporting adverse drug reactions? a. Yes [ ] b. No [ ]

12. What are the barriers to ADR reporting? (Select all that apply)

a. Uncertainty about the cause of ADR [ ] b. Apathy to ADR reporting [ ] c. Not sure of the ADR to report [ ] d. Unavailability of ADR reporting forms [ ] e. Lack of time and workload [ ] f. Complexity of the form [ ] g. Fear of having caused an ADR [ ] h. Lack of knowledge

about ADR reporting [ ] i. No rewards for reporting a suspected ADR [ ] j. Not being clear on what to do after filling the form [ ]

13. Do you think adverse drug reaction reporting should be improved? Yes [ ] No [ ]

14. How do you think ADR reporting should be improved? (Select all that apply)

a. Regular training on ADR reporting [ ] b. Inclusion of ADR reporting in healthcare professional curriculum [ ] c. Strengthening regulatory policies [ ] d. Regular communication and feedback [ ] e. Improved access to ADR reporting forms and online platforms [ ] f. Increased funding for pharmacovigilance activities [ ] Other: _____

15. Have you heard about the MedSafety Mobile App for adverse drug reactions reporting?

a. Yes [ ] b. No [ ]

**SECTION C: KNOWLEDGE ABOUT DRUG-INDUCED DISEASES**

For each statement in the table below, select one option from the three Likert scale:

a. Yes. b. No. c. I do not know.

| | | | |
|---|---|---|---|
| 1. Gastritis can be induced by taking nonsteroidal anti-inflammatory drugs. | Yes ☐ | No ☐ | I do not know. ☐ |

| | | | |
|---|---|---|---|
| 2. Paralytic ileus can be induced by taking loperamide. | Yes ☐ | No ☐ | I do not know. ☐ |
| 3. Hypotension can be induced by taking ceftriaxone injection. | Yes ☐ | No ☐ | I do not know. ☐ |
| 4. Hyponatremia leading to ischemic heart disease can be induced by taking carbamazepine. | Yes ☐ | No ☐ | I do not know. ☐ |
| 5. Parkinsonism can be induced by taking cinnarizine. | Yes ☐ | No ☐ | I do not know. ☐ |
| 6. Obesity can be induced by taking risperidone. | Yes ☐ | No ☐ | I do not know. ☐ |
| 7. Dyslipidaemia can be induced by taking steroids (like estrogens and androgens. | Yes ☐ | No ☐ | I do not know. ☐ |

| | | | |
|---|---|---|---|
| 8. Rhinitis can be induced by taking beta-blockers. | Yes ☐ | No ☐ | I do not know. ☐ |
| 9. Pruritis can be induced by taking angiotensin-converting enzyme inhibitors. | Yes ☐ | No ☐ | I do not know. ☐ |
| 10. Osteoporosis can be induced by taking methotrexate. | Yes ☐ | No ☐ | I do not know. ☐ |

**SECTION D: ATTITUDE TOWARDS ADVERSE DRUG REACTIONS REPORTING**

For each statement in the table below, select one option from the five Likert scale:

a. Strongly agree. b. Agree. c. Neutral. d. Disagree. e. Strongly disagree.

| | | | | | |
|---|---|---|---|---|---|
| 1. ADR reporting is very important, it improves medication safety and patient outcomes. | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |

| | | | | | |
|---|---|---|---|---|---|
| 2. I'm satisfied that I received sufficient education/training about drug-induced diseases and I have enough knowledge about drug-induced diseases. | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |
| 3. As a community pharmacist, I have a responsibility to report adverse drug reactions to the National Agency for Food and Drug Administration and Control. | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |
| 4. I feel confident in my ability to identify adverse drug reactions. | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |
| 5. I am motivated to report adverse drug reactions in my practice. | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |

| | | | | | |
|---|---|---|---|---|---|
| 6. I am uncertain about recommending stopping the drug that I absolutely know its association with the reported problem by the patient. | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |
| 7. ADR reporting is time-consuming and burdensome | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |
| 8. I am concerned about potential legal implications of reporting ADRs. | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |
| 9. As a community pharmacist, I should only be required to consult the prescribing physician when a patient reports any problem associated to certain drugs | Strongly agree ☐ | Agree ☐ | Neutral ☐ | Disagree ☐ | Strongly disagree ☐ |
| 10. I think adverse drug reactions reporting could be improved in | Strongly agree | Agree | Neutral | Disagree | Strongly disagree |

| | | | | | |
|---|---|---|---|---|---|
| community practice setting. | ☐ | ☐ | ☐ | ☐ | ☐ |

**SECTION E: PRACTICE OF ADVERSE DRUG REACTIONS REPORTING**

For each statement in the table below, select one option from the three Likert scale:

a. Always. b. Sometimes. c. Never.

| | | | |
|---|---|---|---|
| 1. Do you review patient's medication list? | Always ☐ | Sometimes ☐ | Never ☐ |
| 2. If patients tell you about symptoms which occur with them, do you ask them about their medication list? | Always ☐ | Sometimes ☐ | Never ☐ |
| 3. When a new medication is introduced to the Nigerian market, do you counsel the patients on potential ADRs when dispensing the medication and do you ask patients who are taking this medication if they experienced any side effects from it? | Always ☐ | Sometimes ☐ | Never ☐ |
| 4. During your professional career, do you record the | Always | Sometimes | Never |

| | | | |
|---|---|---|---|
| reported adverse drug reactions from patients on patients' medical records? | ☐ | ☐ | ☐ |
| 5. How often do you report adverse drug reactions in your community practice to the national pharmacovigilance center ? | Always ☐ | Sometimes ☐ | Never ☐ |
| 6. When you identify a serious ADR, how often do you notify the patient's healthcare provider? | Always ☐ | Sometimes ☐ | Never ☐ |
| 7. How often do you follow up with patients who have experienced an ADR to monitor their condition? | Always ☐ | Sometimes ☐ | Never ☐ |
| 8. How often do you use standardized ADR reporting forms or yellow forms when submitting reports? | Always ☐ | Sometimes ☐ | Never ☐ |
| 9. How often do you use electronic reporting systems for ADR reporting? | Always ☐ | Sometimes ☐ | Never ☐ |

| | | | |
|---|---|---|---|
| 10. When encountering a patient with a known ADR, how often do you adjust their medication regimen accordingly or withdraw the medication? | Always ☐ | Sometimes ☐ | Never ☐ |
| 11. Do you discuss ADR reporting with your colleagues? | Always ☐ | Sometimes ☐ | Never ☐ |
| 12. Do you participate in training or educational programs on ADR reporting? | Always ☐ | Sometimes ☐ | Never ☐ |