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The Role of the Consultant Pharmacist in Pharmacovigilance: Enhancing Medication Safety and Public Health

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Abstract

Pharmacovigilance is essential for ensuring the continued safety and efficacy of pharmaceuticals, particularly in post-marketing settings where adverse drug reactions (ADRs) may emerge beyond controlled clinical trial conditions. In Nigeria, Consultant Pharmacists have become central actors in advancing pharmacovigilance practice. Equipped with advanced qualifications such as the MPharm (Clinical) and FWAPCP, and formally recognized by the National Agency for Food and Drug Administration and Control (NAFDAC) and the Federal Ministry of Health (FMoH), they lead institutional and national efforts in ADR detection, post-marketing surveillance, signal detection, pharmacoepidemiology, risk management, and patient safety. This article examines the evolving role of Consultant Pharmacists as pharmacovigilance leaders, educators, policy influencers, and clinical collaborators. Despite their expanding influence, significant challenges persist, including underreporting, limited digital infrastructure, and gaps in pharmacovigilance education among community members. Strengthening the integration of Consultant Pharmacists into healthcare governance structures is vital for building a resilient, safety-focused pharmaceutical care system. Their contributions are pivotal not only for

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ensuring regulatory compliance but also for safeguarding public health and enhancing the quality of pharmaceutical care delivery.

Keywords: Consultant Pharmacists; Pharmacovigilance; Adverse Drug Reactions; Post-Marketing Surveillance; Patient Safety; Nigeria

Introduction

Pharmacovigilance (PV), as defined by the World Health Organization (WHO), encompasses the science and activities focused on the detection, assessment, understanding, and prevention of adverse effects or any drug-related issues(Jeetu & Anusha, 2010; Kumar, 2017; WHO, 2025). This is vital for ensuring patient safety(Jeetu & Anusha, 2010). In Nigeria, as the healthcare system progresses toward evidence-based, patient-centered care, the Consultant Pharmacist has emerged as a crucial figure in spearheading pharmacovigilance strategies and drug safety interventions(Adenuga *et al.,* 2020).

Expanded Role in Pharmacovigilance

ADR Detection, Documentation & Reporting

Pharmacists are often the first to detect adverse drug reactions (ADRs), and Consultant Pharmacists are well-positioned to lead institutional efforts in documenting and reporting these reactions (Moyo et al., 2023). The pharmacists significantly contribute by identifying, recording, and communicating suspected ADRs, which is a core activity of pharmacovigilance (MG et al., 2016). In clinical practice, the process typically begins during routine patient care activities, such as ward rounds, medication reviews, or counseling sessions, where pharmacists may observe symptoms or receive patient complaints suggestive of ADRs. When an ADR is suspected, the Consultant Pharmacist or the pharmacist conducts a preliminary assessment using standard causality assessment tools (e.g., WHO-UMC or Naranjo algorithm) to evaluate the likelihood that the reaction is drug-related.

Once validated, the pharmacist completes an ADR report using the NAFDAC Yellow Form, either in hard copy or electronically through the Med Safety App. These reports include detailed information such as the patient's clinical condition, the suspected drug(s), the nature of the reaction, onset timing, management given, and outcomes.

Consultant Pharmacists also follow up with the treating clinicians to review the event, update the patient's records, and if necessary, recommend therapeutic substitutions or additional monitoring.

At the institutional level, the pharmacy-led Pharmacovigilance Desk or Drug Information Unit (DIU) collates these reports, maintains a local ADR logbook, and submits consolidated reports to the National Pharmacovigilance Centre (NPC) under NAFDAC. Regular feedback, training, and awareness campaigns are also conducted to encourage healthcare workers to promptly identify and report ADRs. Through this structured process, Consultant Pharmacists play a vital role in strengthening pharmacovigilance systems and ensuring patient safety within the healthcare facility.

Bridging Pre- and Post-Marketing Surveillance

Clinical trials often involve specific populations and limited timeframes. Consultant Pharmacists play an essential role in post-marketing surveillance, identifying rare or long-term adverse effects that may not have been detected during pre-marketing studies(Tech Diary, 2025). Their training allows them to analyze real-world safety data and identify signals that could prevent widespread harm(NAFDAC, 2024b). During the COVID-19 outbreak in Sokoto, Consultant Pharmacists at UDUTH Sokoto, played a key role in post-marketing surveillance of COVID-19 vaccines. Recognizing that clinical trials often miss rare or long-term adverse effects, they monitored vaccine recipients for adverse events following immunization (AEFI). Through the Pharmacovigilance Desk and Drug Information Unit (DIU), they trained healthcare workers on using the NAFDAC Yellow Form and Med Safety App, documented suspected reactions, and ensured timely reporting to national authorities. Their analysis of real-world safety data helped identify trends among vulnerable groups, informed hospital safety protocols, and strengthened public confidence in the vaccination process. This highlights the essential role of Consultant Pharmacists in bridging the gap between clinical trial data and real-world medicine use.

Integration of Pharmacovigilance into Clinical Practice

Pharmacovigilance is no longer confined to pharmacology departments, it is a clinical discipline, and Consultant Pharmacists integrate it directly into ward rounds, medication reviews, and discharge counseling(Celi et al., 2014). They also incorporate PV indicators into hospital quality assurance programs(Abraham et al., 2023; Adenuga et al., 2020). At UDUTH, Consultant Pharmacists have effectively integrated pharmacovigilance

into routine clinical practice by actively participating in weekly ward rounds and medication reviews across key departments such as the Infectious Disease Clinic and Antenatal Clinic. During these sessions, they assess patients for potential adverse drug reactions (ADRs), document findings, and provide real-time therapeutic recommendations to the clinical team. At discharge, they offer targeted counseling on expected side effects and educate patients on how to report ADRs using tools like the Med Safety App. In addition, they collate all documented ADR forms from various clinical units and submit them weekly to the Drug Information Unit (DIU) for proper recording, analysis, and onward reporting to the National Pharmacovigilance Centre (NPC). Pharmacovigilance indicators—such as the number of ADRs reported and high-risk drug monitoring—are also incorporated into the hospital's quality assurance programs, reinforcing PV as a core component of patient safety and clinical governance.

Training and Knowledge Dissemination

Recent studies have emphasized a significant lack of awareness among pharmacists regarding the processes for reporting adverse drug reactions (ADRs). Notably, it has been observed that 77% of pharmacists have never engaged in the reporting of ADRs, raising concerns about the implications for pharmacovigilance and patient safety.(MG *et al.,* 2016). Consultant Pharmacists play a vital role in addressing the existing gap in pharmacovigilance by facilitating comprehensive training sessions, continuing medical education (CME) workshops, and seminars focused on adverse drug reaction (ADR) identification, causality assessment, and the appropriate reporting mechanisms. These initiatives utilize established tools such as the National Agency for Food and Drug Administration and Control (NAFDAC) Yellow Form and the Med Safety App, thereby enhancing the capacity of healthcare professionals to effectively recognize and report ADRs(NAFDAC, 2024a).

Usmanu Danfodiyo University Teaching Hospital (UDUTH), particularly through its Pharmacy Department, has actively advanced pharmacovigilance through consistent training and knowledge-sharing initiatives. In both past and recent efforts, the department has organized workshops on the use of Adverse Drug Reaction (ADR) reporting tools such as the NAFDAC Yellow Form and the Med Safety App. These capacity-building efforts, delivered through clinical presentations have enhanced awareness among healthcare workers and strengthened spontaneous ADR reporting. As part of the initiative, ADR forms were distributed to key pharmacy and hospital units, including the Infectious Disease

Clinic, GOPD, Antenatal Clinic, and ICH, while the Med Safety App was also installed on designated devices to enable prompt and efficient reporting. These efforts, led by Consultant Pharmacists, have fostered a culture of safety and contributed meaningfully to national pharmacovigilance and patient safety goals.

Data Analysis, Signal Detection & Pharmacoepidemiology

Consultant pharmacists possess the capacity to initiate pharmacoepidemiological studies, thereby contributing to evidence-based modifications of formularies and treatment protocols(Bérard, 2021). Their advanced analytical skills facilitate the detection of safety signals, enabling them to provide timely advice on risk-benefit assessments in clinical practice.(Jeetu & Anusha, 2010) At UDUTH, Consultant Pharmacists analyzed reported ADR data related to antituberculosis medications and identified a pattern of peripheral neuropathy in patients receiving isoniazid without adequate pyridoxine supplementation. This safety signal, detected through routine ADR documentation and weekly DIU reports, led to a pharmacoepidemiological review and the recommendation to revise the hospital's TB treatment protocol by mandating pyridoxine co-prescription. This evidence-based intervention improved patient outcomes and highlighted the critical role of Consultant Pharmacists in data-driven decision-making and risk minimization.

Patient Counseling

Creating a supportive and knowledgeable environment during patient counseling is essential for Consultant Pharmacists, as it significantly minimizes the incidence of medication errors and enhances adherence to prescribed regimens(Mutair et al., 2021). By providing comprehensive education, these pharmacists empower patients, particularly those within high-risk populations, to recognize and report side effects that are very harmful. This approach not only safeguards patient health but also fosters a collaborative relationship between pharmacists and patients, ultimately contributing to improved health outcomes(Cousins & Heath, 2008). During patient counseling for example, particularly for patients on chronic therapies such as antiretroviral (HIV) and anti-tuberculosis (TB) medications. Counseling covers the purpose of each drug, correct dosage, timing, and duration of therapy. Patients are educated on potential side effects, including specific adverse drug reactions (ADRs) common with HIV medications such as skin rashes, gastrointestinal upset, liver toxicity, and lipodystrophy as well as TB medications, which may cause peripheral neuropathy, hepatotoxicity, or orange-colored urine. Emphasis is

placed on early recognition and prompt reporting of these ADRs to their physician or pharmacist. Pharmacists also address drug-drug and food-drug interactions (e.g., with rifampicin or efavirenz), provide adherence support strategies, and personalize advice based on pregnancy status, comorbidities, or allergies. Monitoring requirements and signs requiring urgent medical attention are discussed, along with practical lifestyle guidance.

Development of Drug Safety Communication Tools

Consultant pharmacists play a pivotal role in the function of Drug Information and Poison Centres (DIPCs) by generating newsletters, bulletins, and safety alerts tailored for dissemination among clinicians, nursing staff, and pharmacy personnel. This proactive communication promotes the swift distribution of risk-related information within healthcare institutions, thereby enhancing patient safety and clinical decision-making (Jeetu & Anusha, 2010). The Drug Information Unit (DIU) has been successfully established within the Department of Pharmaceutical services, UDUTH Sokoto, as a strategic initiative of the Head of Department (HOD), with full support from the Chief Medical Director (CMD). The DIU, which is fully functional and plays a critical role in promoting rational drug use, medication safety, and pharmacovigilance. Staffed by trained clinical pharmacists, the unit provides reliable drug information to healthcare professionals and patients. It is equipped with essential drug reference materials, including both hardcopy and softcopy resources such as the British National Formulary (BNF), Martindale, and clinical pharmacology texts. The unit also has internet access and maintains links to trusted online drug information platforms. The DIU actively supports adverse drug reaction (ADR) reporting and facilitates the use of tools such as the NAFDAC Yellow Form and Med Safety App. To ensure timely communication, drug alerts, treatment guidelines, and evidence-based responses are disseminated monthly across clinical departments and are also published quarterly in the hospital's internal magazine or bulletin, reinforcing a culture of continuous education and patient safety.

Policy Advocacy and Institutional Leadership

With growing recognition by FMoH, Consultant Pharmacists now influence policies by actively involving in health system frameworks(Abubakar et al., 2022; Croke &Ogbuoji, 2024). For example, in UDUTH Sokoto, pharmacists have played a pivotal role in advocating for the institutionalization of drug information and pharmacovigilance services within the hospital system. Their active involvement in promoting medication

safety and rational drug use has successfully influenced the Chief Medical Director (CMD) to provide financial support for the establishment and operation of the Drug Information Unit (DIU). Through regular collaboration and policy engagement, they have also gained the support of the Chairman, Medical Advisory Committee (CMAC), leading to the DIU's integration into core clinical and administrative functions. As a result of this advocacy, a monthly allocation or imprest is now provided to the Department of Pharmaceutical services for running the DIU. This support covers critical needs such as internet data subscriptions, LAN network services, and the printing of drug safety bulletins, educational materials, and ADR reporting forms. These provisions have ensured the continuous, efficient operation of the DIU and its ability to deliver real-time, evidence-based drug information across departments.

Challenges and Call to Action

Although Consultant Pharmacists have significant potential, their full integration into pharmacovigilance is hindered by several factors, including underreporting, a lack of structured pharmacovigilance education in undergraduate programs, and inadequate IT infrastructure. Overcoming these challenges necessitates enhanced institutional support, broader recognition of the roles of Consultant Pharmacists, and their mandatory inclusion in hospital governance and safety committees.(Menang *et al.,* 2023; Moyo *et al.,* 2023).

Conclusion

The role of the Consultant Pharmacist has evolved beyond that of a mere medicine expert; they now serve as advocates for patient safety, leaders in pharmacovigilance, and influencers of policy. With qualifications such as MPharm, FWAPCP, and recognition by the FMoH and NAFDAC, they are uniquely positioned to enhance Nigeria's pharmacovigilance framework. Strengthening their involvement in pharmacovigilance systems is not only advantageous but essential for ensuring safe, effective, and equitable healthcare delivery.

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