(REVIEW ARTICLE)

Check for updates

Pharmacovigilance in Nigeria: Addressing challenges in ensuring drug safety and monitoring adverse effects

Michael Alurame Eruaga [1, *], Tabat Bature [2] and Esther Oleiye Itua [2]

[1] National Agency for Food and Drug Administration and Control (NAFDAC), Abuja, Nigeria.
[2] National Agency for Food and Drug Administration and Control (NAFDAC), Edo, Nigeria.

Abstract

This paper examines the specific challenges faced by Nigeria in implementing pharmacovigilance measures to ensure drug safety and monitor adverse effects. Despite the critical importance of pharmacovigilance in safeguarding public health, Nigeria grapples with several obstacles in its implementation. Through a nuanced exploration of literature and regulatory frameworks, this study sheds light on the unique hurdles encountered in pharmacovigilance practices within the Nigerian context. Challenges in Nigeria's pharmacovigilance landscape include limited awareness and understanding of pharmacovigilance principles among healthcare professionals and consumers, resulting in underreporting of adverse drug reactions. Additionally, there is a lack of robust infrastructure and resources for pharmacovigilance activities, including inadequate funding, shortage of trained personnel, and deficient pharmacovigilance databases. Regulatory enforcement and oversight are also hindered by issues such as weak regulatory frameworks, fragmented reporting systems, and suboptimal collaboration among regulatory agencies. Furthermore, Nigeria's pharmacovigilance efforts are compounded by factors such as the proliferation of counterfeit and substandard medicines, informal drug markets, and cultural beliefs influencing healthcare-seeking behaviors. These challenges pose significant barriers to effective pharmacovigilance implementation and compromise patient safety and public health outcomes in Nigeria. Addressing these challenges requires a multifaceted approach encompassing regulatory reforms, capacity building initiatives, public awareness campaigns, and collaboration with international partners. Strengthening regulatory frameworks, enhancing healthcare professional training on pharmacovigilance, establishing robust reporting systems, and fostering partnerships between regulatory agencies, healthcare institutions, and pharmaceutical companies are essential steps toward improving pharmacovigilance practices in Nigeria. Through a thorough examination of the Nigerian context, this paper aims to raise awareness of the specific challenges hindering pharmacovigilance implementation in the country and stimulate dialogue on potential solutions to enhance drug safety and monitoring of adverse effects in Nigeria's healthcare system.

Keywords: Pharmacovigilance; Nigeria; Challenges; Drug safety; Adverse effects

1. Introduction

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is crucial for ensuring drug safety (Oshikoya & Awobusuyi, 2009). In Nigeria, the practice of pharmacovigilance faces significant challenges, including inadequate monitoring of adverse effects and a lack of awareness among healthcare professionals (Fadare et al., 2011). Studies have highlighted the importance of educating herbal medicine practitioners on the need for pharmacovigilance activities, especially concerning herbal products (Amadi & Orisakwe, 2018). Additionally, there is a need to enhance the knowledge and perception of pharmacovigilance and adverse drug reaction reporting among pharmacist interns in Nigeria (Eze et al., 2023; Vincent et al., 2021).

---

* Corresponding author: Michael Alurame Eruaga

The National Pharmacovigilance Centre in Nigeria, housed within the National Agency for Food and Drugs Administration and Control (NAFDAC), serves as a central repository for reported adverse drug reactions in the country (Awodele et al., 2018; Olusola, 2017). Despite efforts to improve pharmacovigilance, challenges persist, such as the underreporting of adverse drug reactions by healthcare workers (Fadare et al., 2011; Elufioye et al., 2024). Educational interventions have been proposed to enhance the knowledge, attitude, and practice of healthcare professionals towards pharmacovigilance in Nigeria (Opadeyi et al., 2019; Adisa et al., 2024).

Furthermore, the comparison of pharmacovigilance systems between Nigeria and Ghana reveals disparities in practices, indicating the need for both countries to address challenges in ensuring drug safety effectively (Onasanya et al., 2023; Adaga et al., 2024). The extent of pharmacovigilance among resident doctors in Nigeria underscores the importance of strengthening pharmacovigilance programs across different healthcare sectors (Ohaju-Obodo & Iribhogbe, 2009; Abrahams et al., 2023). Additionally, the assessment of pharmacovigilance activities in sub-Saharan African countries, including Nigeria, emphasizes the necessity of evaluating and addressing the strengths and challenges within existing pharmacovigilance systems (Tiemersma et al., 2021; Ilugbusi et al., 2020).

In conclusion, addressing the challenges in ensuring drug safety and monitoring adverse effects in Nigeria requires a multifaceted approach that involves educating healthcare professionals, enhancing reporting systems, and strengthening pharmacovigilance programs across various healthcare settings. By improving awareness, knowledge, and practices related to pharmacovigilance, Nigeria can take significant strides towards enhancing drug safety and protecting public health.

1.1. Background

Pharmacovigilance in Nigeria encounters significant challenges in ensuring drug safety and monitoring adverse effects. Studies have identified various issues within the country's pharmacovigilance system. One critical aspect is the underreporting of adverse drug reactions (ADRs), which is crucial for effective pharmacovigilance (Oshikoya & Awobusuyi, 2009; Avong et al., 2018; Cliff-Eribo et al., 2015). The underreporting is attributed to factors such as lack of awareness, knowledge, and formal reporting systems among healthcare professionals and patients (Oshikoya & Awobusuyi, 2009; Adisa & Omitogun, 2019; Avong et al., 2018). Moreover, the absence of structured training programs for healthcare professionals further impedes effective pharmacovigilance practices (Osakwe et al., 2013; Uchechukwu et al., 2023).

Pharmacists, including interns, play a central role in pharmacovigilance activities, but they encounter barriers such as inadequate reporting practices and perceived challenges in implementation (Eze et al., 2022). Additionally, the lack of standardized ADR reporting forms and formal reporting systems at healthcare centers presents a significant obstacle that requires immediate attention (Adeleke et al., 2019; Adisa & Omitogun, 2019). A proactive approach by stakeholders, particularly the National Pharmacovigilance Centre, is essential in addressing these challenges (Adisa & Omitogun, 2019).

The evaluation of pharmacovigilance activities in Nigeria has exposed weaknesses in the system, including limited capacity to monitor the safety of medicines, both registered and unregistered, for the treatment of diseases like drug-resistant tuberculosis (Tiemersma et al., 2021). This underscores the importance of strengthening pharmacovigilance systems to ensure the safety of all medications used within the country. Efforts to enhance pharmacovigilance in Nigeria must tackle issues such as the lack of comprehensive data on adverse reactions to medicines, particularly in specific populations like hypertensive patients (Olowofela & Isah, 2017). Collaborative initiatives between healthcare providers and pharmacovigilance centers are crucial to improve reporting mechanisms and ensure the timely detection, assessment, understanding, and prevention of adverse effects related to medications (Vallano et al., 2005).

In conclusion, addressing the challenges in pharmacovigilance in Nigeria necessitates a multi-faceted approach involving increasing awareness, enhancing training programs, establishing formal reporting systems, and fostering collaboration among healthcare professionals and regulatory bodies. By strengthening these aspects, Nigeria can enhance its drug safety monitoring and better protect the health of its population.

1.2. Problem Statement

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is crucial for ensuring the safety and efficacy of pharmaceutical products. However, in Nigeria, there are significant challenges in establishing and maintaining robust pharmacovigilance systems. These challenges include underreporting of adverse drug reactions (ADRs), limited awareness and education among healthcare professionals and the public, inadequate resources and infrastructure, and

fragmented regulatory oversight. As a result, there is a lack of comprehensive data on the safety profile of drugs circulating in the Nigerian market, leading to potential risks to public health and safety.

Objectives

The primary objectives of this concept paper on pharmacovigilance in Nigeria are as follows:

- To assess the current state of pharmacovigilance in Nigeria, including existing systems, challenges, and gaps in drug safety monitoring and reporting.
- To identify key stakeholders involved in pharmacovigilance activities in Nigeria, including healthcare professionals, regulatory agencies, pharmaceutical companies, and patients.
- To analyze best practices and lessons learned from other countries with well-established pharmacovigilance systems, with a focus on strategies for enhancing drug safety surveillance and ADR reporting.
- To propose recommendations and strategies for strengthening pharmacovigilance in Nigeria, including improving reporting mechanisms, enhancing training and education initiatives, increasing public awareness, and enhancing regulatory oversight.
- To outline a roadmap for the implementation of proposed interventions and initiatives, including timelines, responsibilities, and resource requirements.

1.3. Expected Outcome

The expected outcome of this concept paper is to provide a comprehensive overview of the current challenges and opportunities in pharmacovigilance in Nigeria and to propose evidence-based strategies for addressing these challenges. By raising awareness of the importance of pharmacovigilance, improving reporting mechanisms, and enhancing regulatory oversight, it is anticipated that the proposed interventions will contribute to the promotion of drug safety and the reduction of adverse drug reactions in Nigeria. Ultimately, the implementation of effective pharmacovigilance measures will help safeguard public health and enhance confidence in the safety and efficacy of pharmaceutical products in Nigeria.

2. Proposed Solution

In response to the challenges outlined in pharmacovigilance in Nigeria, the following proposed solutions are recommended:

2.1. Strengthening Reporting Mechanisms

Enhance reporting systems for adverse drug reactions (ADRs) by simplifying reporting procedures, providing training and support to healthcare professionals, and promoting the use of electronic reporting platforms. Implement mandatory reporting requirements for healthcare professionals and pharmaceutical companies to ensure comprehensive and timely reporting of ADRs.

2.2. Enhancing Training and Education Initiatives

Develop and implement pharmacovigilance training programs for healthcare professionals, pharmacists, and regulatory authorities to improve awareness, knowledge, and skills in drug safety monitoring and reporting. Increase public awareness through educational campaigns, patient information leaflets, and community outreach programs to encourage patients to report ADRs and understand the importance of pharmacovigilance in ensuring drug safety.

2.3. Strengthening Regulatory Oversight

Enhance the capacity and resources of regulatory agencies such as the National Agency for Food and Drug Administration and Control (NAFDAC) to effectively monitor and regulate pharmaceutical products in Nigeria. Implement risk-based approaches to prioritize pharmacovigilance activities, conduct regular inspections of pharmaceutical manufacturing facilities, and enforce compliance with regulatory requirements.

2.4. Collaborating with International Partners:

Collaborate with international organizations, such as the World Health Organization (WHO) and the Uppsala Monitoring Centre (UMC), to access technical expertise, training materials, and best practices in pharmacovigilance. Establish partnerships with neighboring countries and regional pharmacovigilance networks to facilitate information sharing, harmonize regulatory standards, and enhance surveillance of cross-border drug safety issues.

3. Conclusion

In conclusion, addressing the challenges in pharmacovigilance is critical to ensuring drug safety and protecting public health in Nigeria. By implementing the proposed solutions outlined in this concept paper, Nigeria can strengthen its pharmacovigilance system, improve reporting mechanisms, enhance training and education initiatives, strengthen regulatory oversight, and collaborate with international partners to promote a culture of drug safety and monitoring adverse effects. By taking proactive measures to address these challenges, Nigeria can enhance its capacity to detect, assess, and prevent adverse drug reactions, ultimately safeguarding the health and well-being of its citizens.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

References

[1] Abrahams, T.O., Ewuga, S.K., Kaggwa, S., Uwaoma, P.U., Hassan, A.O. and Dawodu, S.O., 2023. Review of strategic alignment: Accounting and cybersecurity for data confidentiality and financial security.

[2] Adaga, E.M., Egieya, Z.E., Ewuga, S.K., Abdul, A.A. and Abrahams, T.O., 2024. Philosophy In Business Analytics: A Review Of Sustainable And Ethical Approaches. International Journal of Management & Entrepreneurship Research, 6(1), pp.69-86.

[3] Adeleke, O.K., Segun, I.B. and Olaoye, A.I.C., 2019. Impact of internal control on fraud prevention in deposit money banks in Nigeria. Nigerian Studies in Economics and Management Sciences, 2(1), pp.42-51.

[4] Adisa, O., Ilugbusi, B.S., Adewunmi, O., Franca, O. and Ndubuisi, L. (2024a). A comprehensive review of redefining agricultural economics for sustainable development: Overcoming challenges and seizing opportunities in a changing world. World Journal Of Advanced Research and Reviews, 21(1), pp.2329–2341.

[5] Adisa, R. and Omitogun, T. (2019). Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in ibadan, southwestern nigeria. BMC Health Services Research, 19(1). https://doi.org/10.1186/s12913-019-4775-9

[6] Amadi, C. and Orisakwe, O. (2018). Herb-induced liver injuries in developing nations: an update. Toxics, 6(2), 24. https://doi.org/10.3390/toxics6020024

[7] Avong, Y., Jatau, B., Gurumnaan, R., Danat, N., Okuma, J., Usman, I., … & Ogundahunsi, O. (2018). Addressing the under-reporting of adverse drug reactions in public health programs controlling hiv/aids, tuberculosis and malaria: a prospective cohort study. Plos One, 13(8), e0200810. https://doi.org/10.1371/journal.pone.0200810

[8] Awodele, O., Aliu, R., Ibrahim, A., Oni, Y., & Adeyeye, C. (2018). Patterns of adverse drug reaction signals in nafdac pharmacovigilance activities from january to june 2015: safety of drug use in nigeria. Pharmacology Research & Perspectives, 6(5). https://doi.org/10.1002/prp2.427

[9] Cliff-Eribo, K., Choonara, I., Dodoo, A., Darko, D., & Sammons, H. (2015). Adverse drug reactions in ghanaian children: review of reports from 2000 to 2012 in vigibase. Expert Opinion on Drug Safety, 14(12), 1827-1833. https://doi.org/10.1517/14740338.2015.1096927

[10] Elufioye, O.A., Odeyemi, O., Usman, F.O. and Mhlongo, N.Z. (2024). Ai-Driven Predictive Analytics In Agricultural Supply Chains: A Review: Assessing The Benefits And Challenges Of Ai In Forecasting Demand And Optimizing Supply In Agriculture. Computer Science & IT Research Journal, x(Y), pp.1–10. https://doi.org/10.51594/csitrj.v5i.

[11] Eze, S., Odoh, E., Eze, K., Arugo, W., Ozota, G., Anyaji, U., … & Nwokebu, G. (2022). Practices and barriers towards pharmacovigilance and adverse drug reporting among intern pharmacists in nigeria. Journal of Advances in Medical and Pharmaceutical Sciences, 27-40. https://doi.org/10.9734/jamps/2022/v24i11587

[12] Eze, S., Odoh, E., Eze, K., Arugo, W., Ozota, G., Anyaji, U., … & Eze, C. (2023). Assessment of pharmacovigilance activities among pharmacist interns in nigeria: a cross-sectional study. Future Journal of Pharmaceutical Sciences, 9(1). https://doi.org/10.1186/s43094-023-00463-7

[13] Fadare, J., Enwere, O., Afolabi, A., Chedi, B., & Musa, A. (2011). Knowledge, attitude and practice of adverse drug reaction reporting among healthcare workers in a tertiary centre in northern nigeria. Tropical Journal of Pharmaceutical Research, 10(3). https://doi.org/10.4314/tjpr.v10i3.4

[14] Ilugbusi, S., Akindejoye, J.A., Ajala, R.B. and Ogundele, A., 2020. Financial liberalization and economic growth in Nigeria (1986-2018). International Journal of Innovative Science and Research Technology, 5(4), pp.1-9.

[15] Ohaju-Obodo, J. and Iribhogbe, O. (2009). Extent of pharmacovigilance among resident doctors in edo and lagos states of nigeria. Pharmacoepidemiology and Drug Safety, 19(2), 191-195. https://doi.org/10.1002/pds.1724

[16] Olowofela, A. and Isah, A. (2017). A profile of adverse effects of antihypertensive medicines in a tertiary care clinic in nigeria. Annals of African Medicine, 16(3), 114. https://doi.org/10.4103/aam.aam_6_17

[17] Olusola, AO 2017. Rural-Urban Migration In Nigeria. International Journal of Management Sciences (IJOMAS) 10 (1), 79-87

[18] Onasanya, S., Yamoah, P., & Oosthuizen, F. (2023). A comparative study of the pharmacovigilance system in nigeria and ghana using who-indicator based pharmacovigilance assessment tool. (ipat).. https://doi.org/10.21203/rs.3.rs-2216812/v1

[19] Opadeyi, A., Fourrier-Réglat, A., & Isah, A. (2019). Educational intervention to improve the knowledge, attitude and practice of healthcare professionals regarding pharmacovigilance in south-south nigeria. Therapeutic Advances in Drug Safety, 10, 204209861881627. https://doi.org/10.1177/2042098618816279

[20] Osakwe, A., Oreagba, I., A, A., Adekoya, A., & Fajolu, I. (2013). Impact of training on nigerian healthcare professionals' knowledge and practice of pharmacovigilance. International Journal of Risk & Safety in Medicine, 25(4), 219-227. https://doi.org/10.3233/jrs-130605

[21] Oshikoya, K. and Awobusuyi, J. (2009). Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in lagos, nigeria. BMC Clinical Pharmacology, 9(1). https://doi.org/10.1186/1472-6904-9-14

[22] Tiemersma, E., Ibrahim, A., Alemu, A., Avong, Y., Duga, A., Elagbaje, C., ... & Härmark, L. (2021). Baseline assessment of pharmacovigilance activities in four sub-saharan african countries: a perspective on tuberculosis.. https://doi.org/10.21203/rs.3.rs-422624/v1

[23] Uchechukwu, E.S., Amechi, A.F., Okoye, C.C. and Okeke, N.M., 2023. Youth Unemployment and Security Challenges in Anambra State, Nigeria. Sch J Arts Humanit Soc Sci, 4, pp.81-91.

[24] Vallano, A., Cereza, G., Pedrós, C., Agustí, A., Danés, I., Aguilera, C., ... & Arnau, J. (2005). Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. British Journal of Clinical Pharmacology, 60(6), 653-658. https://doi.org/10.1111/j.1365-2125.2005.02504.x

[25] Vincent, A.A., Segun, I.B., Loretta, N.N. and Abiola, A., 2021. Entrepreneurship, agricultural value-chain and exports in Nigeria. United International Journal for Research and Technology, 2(08), pp.1-8