Review Article

Strengthening pharmacovigilance systems through post-vaccination surveillance in Nigeria: A narrative review

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Abstract

Immunization remains a vital pillar of Nigeria's public health agenda, significantly reducing the burden of vaccine-preventable diseases. However, the success of immunization programs hinges not only on vaccine access and delivery but also on robust post-vaccination surveillance systems that ensure vaccine safety and foster public confidence. In Nigeria, post-vaccination pharmacovigilance, led by the National Agency for Food and Drug Administration and Control (NAFDAC), faces critical challenges, including underreporting of adverse events following immunization (AEFIs), inadequate healthcare worker training, infrastructural limitations, and the widespread influence of misinformation. These systemic weaknesses threaten to undermine vaccine confidence, particularly in underserved and rural areas. The aim of this study was to examine the current state of Nigeria's post-vaccination surveillance infrastructure, highlighting gaps in AEFI reporting and data management. Drawing on global best practices and successful models from other low- and middle-income countries (LMICs), this study proposes a set of strategic interventions to strengthen pharmacovigilance. These include the adoption of digital and mobile health technologies, capacity building for healthcare providers, community engagement, and integration of artificial intelligence in safety signal detection. This study underscores the urgency of regulatory reform and private sector inclusion, advocating a holistic and sustainable approach to vaccine safety monitoring. By reinforcing pharmacovigilance systems, Nigeria can build public confidence, improve vaccine uptake, and enhance the overall effectiveness of its national immunization program.

Keywords: Pharmacovigilance, vaccine safety, post-vaccination surveillance, digital health tools, immunization programs

Introduction

Immunization programs are a cornerstone of Nigeria's public health strategy and are pivotal in controlling vaccine-preventable diseases, such as measles, polio, yellow fever, and, more recently, coronavirus disease 2019 (COVID-19) [1]. Nigeria's Expanded Programme on Immunization (EPI), launched in 1979, has significantly scaled up vaccine delivery across urban and rural populations, contributing to a 60% reduction in under-five mortality from vaccine-preventable

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diseases since 2000 [2]. Despite these gains, persistent challenges, including logistical barriers, cold chain inefficiencies, and vaccine hesitancy, continue to hinder optimal immunization coverage, particularly in underserved regions [3,4]. A critical yet often underemphasized component of immunization success is post-vaccination surveillance, which ensures continuous monitoring of vaccine safety and efficacy after widespread administration [5]. Pharmacovigilance systems, designed to detect, assess, and respond to Adverse Events Following Immunization (AEFI), are essential for maintaining public trust and program credibility. Weak post-vaccination surveillance has far-reaching consequences. Failure to promptly detect and transparently address AEFIs can erode public confidence and fuel vaccine hesitancy [6]. For example, during the early stages of the COVID-19 vaccine distribution, misinformation, notably through social media, mistakenly linked the vaccine to paralysis, causing widespread anxiety in rural communities. This led to a 30% drop in scheduled vaccinations within two weeks in some regions [7]. Conversely, areas with active and responsive pharmacovigilance systems saw improved public trust and higher vaccine uptake owing to timely communication and reassurance [8]. However, Nigeria's current pharmacovigilance infrastructure is constrained by underreporting, limited digital integration, workforce shortages, and rapid proliferation of misinformation [9,10]. If these gaps are not addressed, they risk undermining vaccine safety and community trust [11]. This study highlights the current state of post-vaccination surveillance in Nigeria, identifies key challenges, and proposes strategic, evidence-based interventions to strengthen the national pharmacovigilance system. Drawing on lessons from other low- and middle-income countries (LMICs), it highlights pathways toward building a more resilient and trusted immunization program.

Current landscape of pharmacovigilance in Nigeria

The current landscape of pharmacovigilance in Nigeria reveals both progress and persistent challenges in ensuring drug safety and monitoring adverse effects. Nigeria's admission into the World Health Organization (WHO) International Drug Monitoring Programme in 2004 marked a significant step in recognizing the importance of medicine safety [12]. Despite this, the Nigerian pharmacovigilance system continues to grapple with issues such as low spontaneous reporting rates, inadequate training, and funding [9].

The post-vaccination safety monitoring in Nigeria is led by the National Agency for Food and Drug Administration and Control (NAFDAC). The agency operates through a decentralized structure that includes state offices and collaborates closely with the National Pharmacovigilance Centre (NPC) (**Figure 1**). The NAFDAC oversees the collection, assessment, and dissemination of data on AEFIs across the country [13]. NAFDAC's pharmacovigilance operations were notably scaled during the COVID-19 pandemic, with the establishment of dedicated reporting forms, toll-free lines, and integration of digital dashboards for real-time AEFI tracking [14]. A key innovation was the COVID-19 AEFI Dashboard, developed in collaboration with multiple health partners, which triangulated data from multiple sources to enhance decision-making [15]. However, this structure is not without challenges. While NAFDAC provides a national framework, actual data reporting is often inconsistent across states due to limited training, technological gaps, and bureaucratic delays. Additionally, the NPC lacks the financial autonomy and human resource capacity to operate independently and proactively in all regions [16].

Despite its critical role in maintaining medication safety, pharmacovigilance in Nigeria, governed by the NAFDAC, faces numerous obstacles [9,10]. Studies and reviews of NAFDAC's pharmacovigilance system, particularly when compared to WHO's minimal requirements and international standards, reveal areas of limitations and inadequacies [17]. A significant challenge is the very low rate of spontaneous reporting of adverse drug reactions (ADRs) [18]. This can be attributed to several factors, including limited awareness among healthcare professionals and the general population [18,19], as well as the complexity of the existing reporting system. Many pharmacovigilance centers in Nigeria lack sufficient financial and operational resources to carry out their functions effectively [20]. Insufficient training for healthcare professionals and inadequate funding for PV activities further exacerbate the problem [9]. Evidence indicates that targeted training programs have been shown to significantly improve knowledge and practice among healthcare professionals [21], underscoring the importance of continuous education.

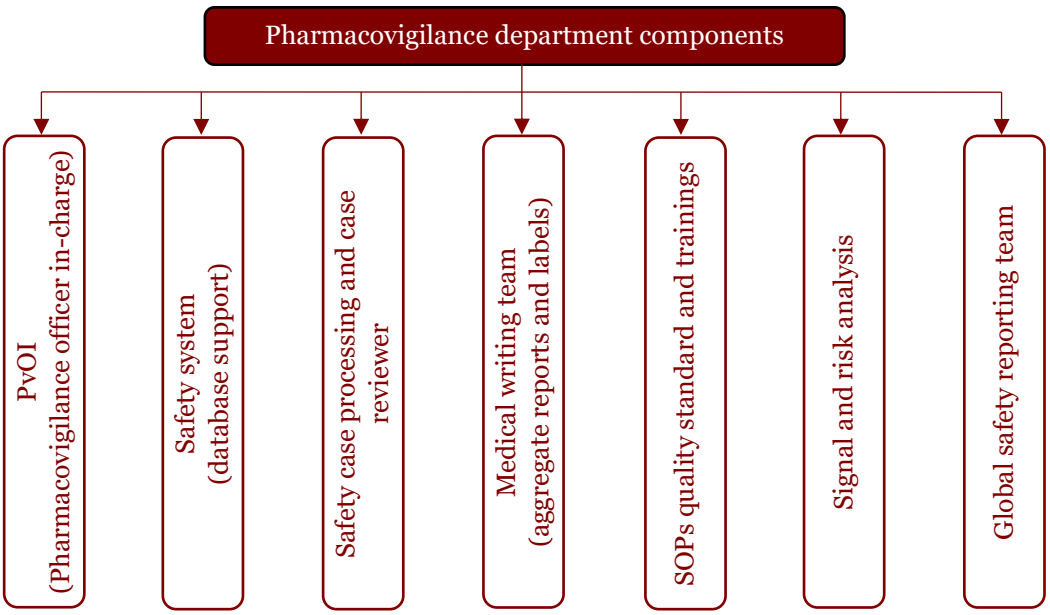

Figure 1. Schematic diagram of the complete pharmacovigilance system components [22].

Safety monitoring of herbal medicines poses a particular challenge, given the inadequate state of the pharmacovigilance systems for herbal medicines [23]. There is a need for improvements in legislation, expanding awareness and education, and adapting coding systems for herbal products [24]. While digital health technologies offer potential solutions, their implementation in the Nigerian healthcare system is hindered by limited infrastructure and labour shortages [25]. Stakeholder engagement is therefore critical to the development of effective pharmaceutical safety systems in Nigeria [26]. A three-day stakeholder workshop conducted in March 2024 employed a qualitative participatory engagement technique to investigate the current state of pharmacovigilance, focusing on major enablers, impediments, and viable strategies [26]. This collaborative approach is vital for recognising and addressing the complex challenges facing Nigeria's pharmacovigilance system. Despite these issues, various attempts are underway to increase the pharmacovigilance in Nigeria. One such initiative is a system implemented by NAFDAC to facilitate direct consumer reporting of suspected ADRs [27]. The NAFDAC also collaborates with international organizations such as the WHO to enhance its pharmacovigilance system and align it with international standards [28].

Although Nigeria has made progress in developing a pharmacovigilance system, significant limitations persist, including underreporting of ADRs, insufficient resources, and gaps in data management and public awareness. Addressing these concerns through focused interventions, such as improved training, enhanced data management systems, and increased stakeholder participation, is critical for boosting pharmacovigilance and guaranteeing medication safety in Nigeria [9]. These initiatives reflect an integrated pharmacovigilance automation framework that combines trained personnel, information technology infrastructure, and systematic testing and validation processes, as illustrated in **Figure 2**.

Challenges facing post-vaccination surveillance in Nigeria

One of the most critical issues undermining Nigeria's vaccine safety framework is the underreporting of AEFIs. A recent study conducted in Sokoto State found that although 81.3% of respondents experienced at least one post-vaccination event, a large proportion failed to report them due to a lack of awareness or mistrust in the system [13]. Data quality issues are compounded by the absence of electronic health record systems in most primary healthcare centers. AEFI reports are often filed manually, stored on paper, and not digitized, creating serious limitations for timely data aggregation and trend analyses [11].

Health workers, particularly those in remote areas, frequently lack training in pharmacovigilance. Many are unaware of the correct procedures for identifying, documenting, and escalating adverse event reports. Even when trained, high staff turnover rates and workload

pressures make sustained implementation difficult [10]. This lack of capacity diminishes the quality of surveillance and undermines the community's trust. When healthcare providers dismiss or downplay AEFIs, it fuels rumors and increases vaccine hesitancy [16].

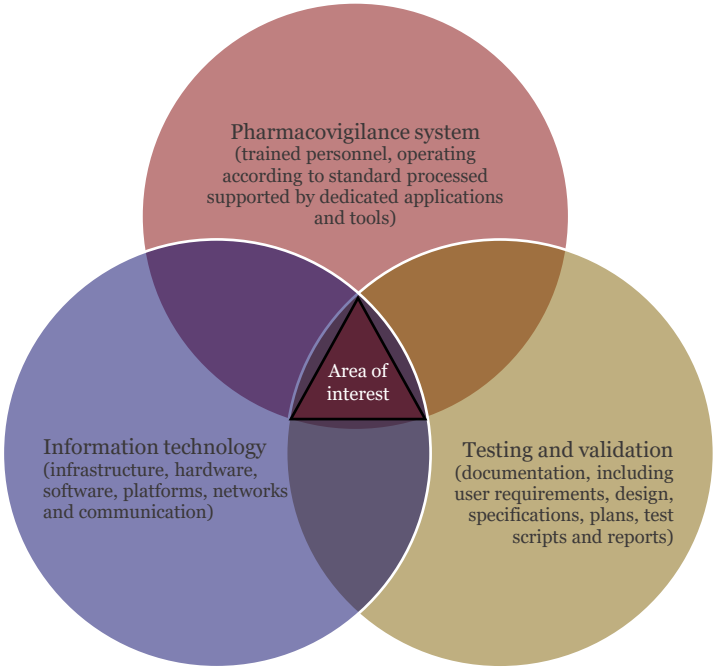

Figure 2. Conceptual diagram illustrating the entities involved in the pharmacovigilance system automation [29].

The lack of stable electricity, reliable internet access, and mobile network connectivity in many Nigerian health centers significantly hampers the deployment of digital reporting platforms, thereby undermining efforts to improve healthcare quality and accessibility [30]. Additionally, even where digital tools, such as the Med Safety App or DHIS2-based reporting systems, are available, limited digital literacy among workers hinders their uptake [15]. Moreover, even successful initiatives, such as NAFDAC's real-time dashboards, face integration issues with other health data systems, such as those maintained by the Nigeria Centre for Disease Control (NCDC) or the National Primary Health Care Development Agency (NPHCDA), reducing the efficiency of national-level analysis [31]. Social media platforms and informal information networks have become sources of misinformation regarding vaccine safety, particularly in regions with low literacy levels or historical mistrust of public health interventions. Reports of AEFIs, even when mild or unrelated to vaccines, are amplified and sometimes politicized [32]. Without proactive communication from trusted figures such as religious leaders, local chiefs, or community health volunteers, false narratives often gain traction, leading to a drop in vaccine uptake [11].

Strategies for strengthening pharmacovigilance systems in Nigeria

Enhancing pharmacovigilance in Nigeria requires the integration of technology, strengthening of regulatory frameworks, and engagement of communities to improve AEFI reporting and data management. Given Nigeria's healthcare infrastructure challenges and widespread use of medicine and vaccine, a multifaceted approach is necessary to ensure drug safety and better public health outcomes. Nigeria must transition from paper-based to electronic reporting to improve the efficiency, accuracy, and timeliness of reporting. Digital tools, such as mobile applications and web-based platforms, can streamline data collection and reduce errors. The Med Safety App, already in use in several African countries [33], could be adapted for use by NAFDAC.

However, challenges such as poor Internet connectivity and digital literacy among healthcare workers must be addressed. A hybrid model that combines manual and electronic reporting can be implemented in rural areas. Additionally, partnerships with local telecommunications companies, such as MTN, Globacom, and Airtel, can facilitate SMS-based

reporting, ensuring inclusivity. Training healthcare workers in AEFI identification and reporting is essential for accurate data collection. Additionally, engaging community leaders and traditional rulers can help raise awareness of vaccine safety and foster public trust. Previous research [34] underscores the importance of community-driven pharmacovigilance, which is particularly relevant to Nigeria's diverse and community-oriented healthcare system. By involving local leaders, Nigeria can create a culture of transparency and accountability, encouraging individuals to report adverse events without fear of stigma or misinformation. However, community engagement alone is insufficient without a responsive technical system to support it. A robust pharmacovigilance framework helps address mistrust by ensuring that reported AEFIs are not merely collected but are also visibly investigated and acted upon [6]. When communities observe that safety concerns prompt transparent scientific inquiry, and that findings are communicated back through trusted local leaders, perceptions of the health system can shift from 'passive data collector' to 'active safety guardian.' This feedback loop is essential for converting skepticism into confidence [11]

Moreover, NAFDAC plays a pivotal role in pharmacovigilance, but its capacity must be enhanced. Providing adequate funding, technical support, and training for NAFDAC staff is critical to achieving this goal. Establishing a dedicated vaccine safety department within the NAFDAC would improve oversight and coordination, ensuring that adverse events are investigated and addressed promptly [35]. This department could also serve as a hub for data analysis and the dissemination of safety information to healthcare providers and the public. Furthermore, standardizing AEFI investigation and response protocols is necessary to align Nigeria's national guidelines with the WHO Global Vaccine Safety Initiative (GVSI). Clear guidelines will ensure consistency in reporting and responses across the country. Lessons from the United States, as discussed in the previous study [36], highlight the importance of integrating passive and active surveillance systems to strengthen pharmacovigilance. Nigeria should adopt similar approaches and mandate pharmacovigilance reporting in the private healthcare sector. Many adverse events occur in private hospitals and pharmacies; however, these entities contribute minimally to national reporting systems. Regulatory reforms should require private healthcare providers and pharmaceutical companies to report AEFIs, with incentives for compliance and penalties for noncompliance.

Artificial intelligence (AI) and machine learning (ML) have significant potential for analyzing large datasets to detect safety signals. Nigeria can adapt AI-driven pharmacovigilance systems, such as those used in Brazil, which have improved adverse event detection and response times [37]. Additionally, Nigeria can integrate the VigiFlow system developed by the Uppsala Monitoring Centre, which is already in use in several African countries. VigiFlow is an Individual Case Safety Report (ICSR) management system that supports the electronic capture and transmission of suspected adverse events [38]. VigiFlow streamlines the collection, storage, and analysis of ADR data, thereby enhancing the efficiency of pharmacovigilance systems [39]. For example, Brazil has successfully implemented VigiFlow to strengthen its pharmacovigilance systems. By adopting VigiFlow, Nigeria can improve its capacity to manage ICSRs and detect safety signals more effectively [38]. This system can support Nigeria's pharmacovigilance framework by enabling efficient data management and analysis. Furthermore, given Nigeria's high mobile phone penetration rate, mHealth solutions such as SMS-based or app-based reporting systems can revolutionize AEFI monitoring. For example, Uganda's mTRAC system has leveraged mobile health technology for vaccine safety and pharmacovigilance [40]. By implementing similar systems, Nigeria can enable real-time reporting and improve data accessibility for healthcare providers and policymakers in Nigeria. The Med Safety App was launched in Nigeria in November 2020 to provide an electronic platform for users to seamlessly report AEs [41]. Uganda is also exploring the use of Med Safety to improve ADR reporting by healthcare professionals [42]. Broader adoption of the Med Safety App in Nigeria can empower healthcare professionals and the public to report ADRs more easily, leading to better data collection and analysis [43].

India's Pharmacovigilance Program of India (PvPI) employs a hub-and-spoke model for AEFI reporting, connecting regional pharmacovigilance centers (spokes) to a central coordinating body (the hub) [44]. Nigeria's federal health system could benefit from a similar

regional AEFI reporting structure under the NAFDAC. Additionally, investing in a centralized database for real-time AEFI monitoring would enable rapid responses to potential safety concerns [45]. The National Immunization Safety Expert Committee (NISEC) in South Africa is responsible for causality assessment and AEFI surveillance, ensuring that reported adverse events are thoroughly investigated [46]. Nigeria could establish a similar expert committee under the NAFDAC to improve vaccine safety assessments and public trust. The Democratic Republic of the Congo (DRC) has integrated pharmacovigilance into its national health programs, leveraging technology for real-time ADR reporting, especially in remote areas [47]. Nigeria could replicate this approach by embedding pharmacovigilance into its National Malaria Elimination Program (NMEP) and immunization efforts, leveraging mHealth tools, and training healthcare workers. Kenya has improved vaccine safety surveillance among pregnant women by implementing Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) standards, which standardize case definitions and enhance data collection. A previous feasibility study [48] showed that web-based platforms significantly improved pharmacovigilance and maternal health monitoring. Nigeria could also adopt GAIA standards and integrate vaccine safety into its public health programs.

AI offers promising solutions for enhancing drug safety monitoring and signal detection in pharmacovigilance [49,50]. AI algorithms can analyze vast amounts of data from various sources to identify potential safety signals more efficiently than traditional methods [49,51]. AI can detect subtle patterns and correlations that may indicate emerging drug safety concerns, enabling timely interventions [52]. In Brazil, data mining in large databases like Vigimed/VigiFlow is essential to identify early safety signals and to support pharmacovigilance systems [53]. A cross-sectional study was done to examine adverse medication events associated with antibiotics reporting from December 2018 to December 2021 in the Brazilian database (Vigimed/VigiFlow) [53]. AI algorithms can extract relevant information from unstructured data sources, such as electronic health records and social media, to create comprehensive safety reports [54]. AI can integrate data from diverse sources, including clinical trials, post-marketing surveillance, and patient-reported outcomes, to provide a holistic view of drug safety [55]. AI algorithms can harmonize disparate data formats and identify potential data quality issues, ensuring the reliability of PV data [56]. While the potential of AI is vast, its immediate application in Nigeria requires a realistic assessment of digital readiness. Current infrastructure gaps, particularly the lack of stable electricity and internet connectivity in rural Primary Healthcare Centers (PHCs), pose significant barriers to deploying high-level AI frameworks [57,58]. Therefore, Nigeria's adoption of these technologies must follow a phased 'digital ladder' approach. The immediate priority should be strengthening basic digitization, such as shifting from paper to simple mobile-based reporting (mHealth) in rural areas, to create the reliable data streams that AI requires. Advanced AI analytics should initially be deployed only at the central national level (NAFDAC), where infrastructure is more stable, rather than expecting frontline facilities to support complex digital tools immediately.

Despite the potential benefits of technology and AI, several challenges must be addressed to ensure successful implementation in Nigeria. Ensuring the accuracy and completeness of ADR data is crucial for effective pharmacovigilance systems [59]. Implementing data validation procedures and providing training to healthcare professionals on proper reporting practices could improve data quality [39]. Adequate IT infrastructure is necessary to support the implementation of electronic reporting systems and AI-based tools [60]. Investing in reliable hardware, software, and network connectivity is essential for efficient data management and analysis [60]. Healthcare professionals need to be trained on the use of new technologies and AI tools for pharmacovigilance [39]. Providing regular training programs and mentoring opportunities could enhance their knowledge and skills in ADR reporting and analysis [61]. The adoption of technologies like VigiFlow and Med Safety, coupled with the application of AI, could also enhance the timeliness, accuracy, and efficiency of ADR reporting and analysis, ultimately safeguarding public health [38,43].

Future directions and recommendations

To build a robust post-vaccination surveillance framework, Nigeria must prioritize systemic, technological, and community reform. The following recommendations outline a forward-looking strategy to strengthen pharmacovigilance systems nationwide. To improve the accuracy and efficiency of AEFI reporting, it is essential to strengthen training programs for healthcare workers, particularly those serving remote and underserved areas. Continuous education on vaccine safety, adverse event identification, and the use of digital tools for reporting are crucial. Future research should explore the effectiveness of these training programs and assess their impact on improving data quality and healthcare worker engagement in pharmacovigilance. Transitioning from paper-based to electronic reporting systems is critical for improving the timeliness, accuracy, and efficiency of AEFI data collection in the future. Future research should investigate the feasibility of adapting digital tools, such as the Med Safety App, which has been successful in other African countries, for use in Nigeria. Moreover, studies should focus on overcoming challenges related to Internet connectivity, digital literacy, and the integration of mobile health (mHealth) solutions, such as SMS-based reporting, to reach rural and hard-to-reach areas.

NAFDAC's capacity to manage pharmacovigilance activities must be enhanced through increased funding, technical support, and the establishment of a dedicated vaccine safety department (**Table 1**). Future research should assess the current limitations of NAFDAC's operations and explore strategies for improving its ability to collect, analyze, and respond to AEFI reports. Additionally, studies could evaluate the integration of NAFDAC's pharmacovigilance system with other national health databases, such as those maintained by the Nigeria Centre for Disease Control (NCDC) and the National Primary Health Care Development Agency (NPHCDA).

Table 1. Summary of actions and research focus areas for post-vaccination surveillance reform

Thematic area	Recommendation	Suggested research focus
Healthcare Worker training	Strengthen training on vaccine safety, AEFI identification, and digital tools for healthcare workers, especially in underserved areas.	Evaluate effectiveness of training on data quality and healthcare worker engagement.
Digital reporting systems	Transition from paper-based to digital AEFI reporting (e.g., Med Safety App, mHealth, SMS).	Study feasibility, literacy, internet access, and integration of digital tools in rural settings.
Strengthening NAFDAC	Increase NAFDAC funding, provide technical support, and create a vaccine safety department. Integrate with NCDC and NPHCDA systems.	Assess operational gaps and explore national database integration for better pharmacovigilance.
Community engagement	Use community leaders, influencers, and campaigns to fight misinformation and promote vaccine safety.	Assess effectiveness of community-driven pharmacovigilance and impact of communication strategies.
AI and machine learning	Leverage AI/ML and platforms like VigiFlow for adverse event detection and decision-making.	Explore feasibility and impact of AI/mHealth reporting in Nigeria's immunization programs.
Private sector involvement	Enforce AEFI reporting by private hospitals/pharmacies with incentives and penalties.	Investigate barriers to private reporting and assess regulatory strategies for compliance.
Learning from other LMICs	Adapt successful pharmacovigilance models from India, South Africa, Uganda, etc.	Conduct comparative analysis of LMIC models and tailor them for Nigeria's immunization infrastructure.

AEFI: adverse events following immunization; NAFDAC: National Agency for Food and Drug Administration and Control; NCDC: Nigeria Centre for Disease Control; NPHCDA: National Primary Health Care Development Agency; LMIC: low- and middle-income countries

Addressing vaccine hesitancy, particularly in rural areas, requires targeted public awareness campaigns. Engaging community leaders, local influencers, and healthcare workers to disseminate accurate vaccine safety information can help combat misinformation. Future research should focus on evaluating community-driven pharmacovigilance initiatives and how community leaders can play a role in enhancing trust in the vaccine safety monitoring system. Additionally, studies on the impact of misinformation and the effectiveness of communication strategies in reducing vaccine hesitancy would provide valuable insights. AI and machine learning

offer significant potential for enhancing pharmacovigilance systems in Nigeria. Future research could explore how AI-driven systems can be adapted to detect adverse events from large datasets and improve decision-making. Integrating existing platforms, such as VigiFlow, could help streamline AEFI reporting and data management. Additionally, mobile health solutions, such as app- or SMS-based reporting systems, can revolutionize AEFI monitoring, especially in areas with limited access to the Internet. Future studies should evaluate the feasibility and impact of these technological solutions on Nigeria's immunization programs.

Many adverse events occur in the private healthcare sector; however, these are often underreported. Future research should examine the barriers to AEFI reporting in private hospitals and pharmacies and explore how regulatory frameworks can mandate reporting from these entities. Additionally, studies could evaluate the impact of providing incentives for reporting and penalties for non-compliance to improve the overall national pharmacovigilance system. Drawing lessons from other LMICs, Nigeria can strengthen its pharmacovigilance system by adopting successful models from countries such as India, South Africa, the Democratic Republic of Congo, and Kenya. Research should explore how these models, such as the hub-and-spoke system in India, South Africa's expert committees, and mHealth tools in Uganda, can be adapted to Nigeria's healthcare system. A comparative analysis of these models and their effectiveness in improving vaccine safety monitoring could provide valuable insights for developing a more resilient and trusted immunization system in Nigeria.

Conclusion

Post-vaccination surveillance is a critical component of Nigeria's immunization strategy. Despite notable progress in vaccine delivery, challenges such as underreporting, infrastructural gaps, workforce shortages, and misinformation hinder the full potential of pharmacovigilance. Strengthening pharmacovigilance in Nigeria requires a multifaceted approach that integrates technology, enhances healthcare worker training, and fosters community engagement. By drawing on lessons from other LMICs and adapting innovative solutions, Nigeria can build a more robust, resilient, and trusted immunization framework. In the long term, this will not only enhance vaccine safety monitoring but also contribute to higher vaccination rates, improved public health outcomes, and greater public trust in vaccination programs.

Ethics approval

Not required.

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None to declare.

Competing interests

All the authors declare that there are no conflicts of interest.

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Underlying data

Derived data supporting the findings of this study are available from the corresponding author on request.

Declaration of artificial intelligence use

Artificial intelligence-based language model, Quillbot, was employed for improving the grammar, sentence structure, and readability of the manuscript. We confirm that all AI-assisted processes were critically reviewed by the authors to ensure the integrity and reliability of the results. The final decisions and interpretations presented in this article were solely made by the authors.

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