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# OPTIMIZING VACCINE SAFETY SURVEILLANCE IN NIGERIA: KEY COMPONENTS AND ORGANIZATIONAL STRUCTURES FOR EFFECTIVE ADVERSE EVENT MONITORING

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## ABSTRACT

*The study, Optimizing Vaccine Safety Surveillance in Nigeria: Key Components and Organizational Structures for Effective Adverse Event Monitoring was conducted in the 36 states of the country including the Federal Capital Territory. The study made use of primary data that was collected using structured questionnaire consisting of four research objectives. A total of 412 respondents were sampled using purposive sampling method. The data for the study was analyzed using descriptive statistics of frequencies and percentages. The result showed that there is significant underreporting of adverse events, fragmented data collection, and low stakeholder awareness of global monitoring systems like VAERS. Furthermore, the result identified primary challenges which include; complex reporting processes, resource limitations, and public distrust. Manual reporting remained prevalent despite recognition by most participants that mobile applications and AI-driven tools could enhance efficiency. The study concluded that Nigeria's monitoring system requires strengthening through public education to combat misinformation, simplified digital reporting, improved data integration with existing health systems and investments in training health workers. From the results and conclusions, the study therefore recommends implementation of user-friendly reporting apps, integration of Artificial Intelligence for signal detection and blockchain for secure and transparent data management.*

.**Keywords: Vaccine Safety Surveillance, Event Monitoring.**



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## INTRODUCTION

Vaccination is a cornerstone of public health, preventing morbidity and mortality from vaccine-preventable diseases. However, monitoring the safety of vaccines after deployment is essential to detect rare adverse events, ensure public trust, and respond to safety signals appropriately. In Nigeria, periodic evaluation of vaccine safety surveillance systems remains limited, leading to concerns about their robustness and effectiveness in real-time monitoring and response (Omoleke and Kiev, 2024). Against this backdrop, it is vital to critically appraise existing structures and propose optimization strategies for AEFI surveillance in Nigeria.

Adverse Events Following Immunization (AEFI) refers to any untoward medical occurrence following immunization, which may not necessarily have a causal relationship with vaccine administration (Erekosima et al., 2025). Vaccine Safety Surveillance is the Systematic collection, analysis, and reporting of data on adverse events post-vaccination to detect, assess, understand, and prevent vaccine-related risks (Zhang et al., 2025).

Though Nigeria has established AEFI surveillance mechanisms at the national and sub-national levels, studies indicate sub-optimal performance regarding representativeness, sensitivity, completeness, and the robustness necessary for emerging vaccine rollouts (Omoleke and Kiev, 2024). Challenges include fragmentation of data collection, inadequate feedback mechanisms, insufficient capacity for causality assessment, and limited integration with supply chain technologies (Adeyeye et al., 2024). Effective surveillance requires harmonized digital data systems capable of integrating information from multiple sources. For COVID-19 vaccination, Nigeria utilized a data triangulation approach, consolidating AEFI records from diverse platforms into a centralized dashboard for real-time monitoring, stakeholder review, and rapid decision-making (Shragai et al., 2023). Such integration aligns with WHO guidelines and international best practices for minimum data sets essential for active surveillance systems (Zhang et al., 2025).

Knowledge gaps, insufficient training, and high workload among healthcare workers impede AEFI reporting and surveillance. Designating officers responsible for AEFI, providing continuous education, and supportive supervision are seen as keys to system improvement (Omoleke et al., 2023). In Nigeria, awareness among frontline healthcare workers exists, but knowledge of reporting procedures and event definitions remains inadequate, necessitating ongoing professional development (Umar et al., 2023). From the forgoing, this paper is aimed at, ascertaining the organizational structure that is most effective for monitoring vaccine safety in Nigeria and identifying the key components of effective vaccine adverse effect monitoring system in Nigeria.


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## METHODOLOGY

The data for this study were collected using a well-structured questionnaire administered to respondents through Google Forms. The questionnaire covered all areas of the research questions. A total of 412 respondents were collected for this study. The data was analyzed using descriptive statistics such as frequencies and percentages by utilizing the Statistical Package for Social Sciences (SPSS). .

## RESULTS AND DISCUSSIONS

### System Organization and Implementation

The results on the nature of system for monitoring adverse effects after vaccination is presented in the table 1 below. The result shows that 37.9% of the responses on vaccine adverse effects monitoring system is integrated with existing health information system, 24.5% of the responses shows that the system is independent and stand-Alone system and 37.6% of the responses shows that the system is partially integrated with other health systems. From the result, it can be concluded that most of the monitoring system is integrated with existing health information systems. The finding that 75.5% systems are either integrated or partially integrated corresponds with WHO's Global Vaccine Safety Blueprint 2023, which recommended connecting adverse event monitoring to existing health information systems (HIS) to improve data quality and operational efficiency.

**Table 1.** Nature of system for monitoring adverse effects after vaccination

| Variable | Frequency | Percentage |
|---|---|---|
| Integrated with existing heath information system | 156 | 37.9 |
| Independent and Stand-Alone System | 101 | 24.5 |
| Partially integrated with other health systems | 155 | 37.6 |
| **Total** | **412** | **100** |

**Source:** Author's computation using SPSS

The table 2 below shows the result of the primary methos used for reporting adverse effects. The result shows that 44.2% of the method used is manually done, 27.2% of the method use for reporting is electronically carried out and 28.6% of the method used for reporting is through mobile applications. From the result, it shows that manual reporting (paper-based forms) is most commonly used. The prevalence of manual reporting (44.2%) for adverse effects aligns with findings by Alshammari et al. (2019) in his paper the challenges of transitioning from paper to electronic medical records, who identified barriers like training gaps, financial constraints, workflow resistance, and inefficient data entry as major obstacles which hinder


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the successful adoption of EMRs. This underscores that resolving manual reliance requires not only problem-solving: it requires a shift in organizational commitment, targeted training, as well as cultural changes, to address the multidimensional challenges sustaining paper-based systems.

**Table 2.** Primary method used for reporting adverse effects

| Variable | Frequency | Percentage |
|---|---|---|
| Manual (paper-based forms) | 182 | 44.2 |
| Electronic (EHR Systems, web portal) | 112 | 27.2 |
| Mobile applications | 118 | 28.6 |
| **Total** | **412** | **100** |

**Source:** Author's computation using SPSS

The result for who is responsible for collecting and reporting adverse effects data is presented in the table 3 below. The result shows healthcare providers are responsible for data collection by 26.0%, public health officials are responsible for data collection by 28.2%, vaccine recipients are responsible for data collection by 21.6% and data entry personnel are responsible for data collection by 24.3%. This result shows that data is mostly collected by public health officials. The study by Pitts et al. (2016) tittle pharmacovigilance: efforts, roles and responsibilities, supports multiple stakeholders' involvement in adverse effects data collection, which aligned with this work's findings (28.2% public health officials; 26.0% providers; 21.6% patients). However, it contradicts the conclusion that public health officials are primary collectors by asserting that agencies like the EMA/FDA are mainly the ones analyzing the data rather than being the frontline collectors, thus likely revealing regional system designs. He emphasizes the role of healthcare providers as key frontline reporters within the EU/US systems, whereas they took second place in the data generated in this study. The increasing role of patients in this regard is recognized, but their limited clinical verification speaks to the reasons for providers and officials being prioritized.

**Table 3.** Who is responsible for collecting and reporting adverse effects data?

| Variable | Frequency | Percentage |
|---|---|---|
| Healthcare providers | 107 | 26.0 |
| Public Health Officials | 116 | 28.2 |
| Vaccine Recipients | 89 | 21.6 |
| Data entry personnel | 100 | 24.3 |
| **Total** | **412** | **100** |



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**Source:** Author's computation using SPSS

The result on how often data on adverse effects are updated and reviewed is presented in the table below 4 below. The result shows that data is updated in real time by 21.4%, data is updated daily by 15.3%, data is updated weekly is 21.8%. Furthermore, the data update monthly by 21.4% while update yearly is 20.1%. from the result above, it can be concluded that the data updates are majorly done on weekly bases. The finding that weekly updates (21.8%) are the most frequent method for adverse effects monitoring aligns with Dal Pan et al. (2019), who note that low- and middle-income countries (LMICs) prioritize weekly updates to balance timeliness with resource limitations However, this contrasts with WHO (2021) and EMA (2022) guidelines advocating for real-time or daily updates (as seen in systems like EudraVigilance), reflecting disparities in infrastructure and capacity between LMICs and high-income regions.

**Table 4.** How often is data on adverse effects updated and reviewed?

| **Variable** | **Frequency** | **Percentage** |
|---|---|---|
| In real time | 88 | 21.4 |
| Daily | 63 | 15.3 |
| Weekly | 90 | 21.8 |
| Monthly | 88 | 21.4 |
| Yearly | 83 | 20.1 |
| **Total** | **412** | **100** |

**Source:** Author's computation using SPSS

**Improving Monitoring System**

Table 5 identifies five areas key stakeholders considered for strengthening the monitoring system. The most cited need was in the area of increasing public education (24.5%), followed closely by enhancing system transparency (23.8%). Improving data integration and analysis was identified by 21.4% of respondents, while reporting processes were simplified by 16.5%. A smaller but still significant portion (13.8%) felt that follow-up on reported cases was also necessary. These findings demonstrate that improvements are needed across multiple aspects of the system. The strong focus on public education and transparency suggests stakeholders view better communication and awareness as critical for system effectiveness. Meanwhile, the emphasis on data integration and process simplification points to technical and operational challenges that need addressing. The call for improved case follow-up indicates a desire for more responsive and actionable monitoring. From the results, it can be seen that increase public education will significantly improve the


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monitoring system in Nigeria. Van Hoof et al., in their work titled factors Contributing to Best Practices for Patient Involvement in Pharmacovigilance emphasize on patient education and empowerment as informed patients improve signal detection and mitigate misinformation, trust-building via responsive follow-up, closing feedback loops to demonstrate responsiveness thereby increasing system transparency. All of which demonstrate direct alignment with this review.

**Table 5**. Improvements necessary for monitoring systems

| **Variable** | **Frequency** | **Percentage** |
|---|---|---|
| Simplifying the process | 68 | 16.5 |
| Increasing public education | 101 | 24.5 |
| Enhancing data integration and analysis | 88 | 21.4 |
| Increasing system transparency | 98 | 23.8 |
| Increasing follow-up on reported cases | 57 | 13.8 |
| **Total** | **412** | **100** |

**Source:** Author's computation using SPSS

The result on whether technology improves adverse effects monitoring is presented in table 6. The result shows that majority of respondents (51.7%) stated that technological solutions could enhance the system, while 25.0% of the respondents stated that technology cannot improve adverse effects monitoring. A significant minority (23.3%) were unsure of its role in improving adverse effects monitoring. These results suggest that while technology holds significant promise for improving monitoring systems, its successful integration depends on careful planning and evidence-based validation. Cooper et al. in their work: The International Working Group on New Developments in Pharmacovigilance note that the IWG is advancing AI-driven causality assessment and data source integration which aligns with the 51.7% of respondents who affirm technology's role in enhancing pharmacovigilance monitoring. This review also aligns with documented advancements like WHO's VigiFlow/VigiMobile (enabling real-time global AE reporting) and AI-driven analytics (e.g., VigiLyze for signal detection), which demonstrably improve speed, accuracy, and scalability of monitoring.


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**Table 6.** Can technology improve adverse effects monitoring?

| Variable | Frequency | Percentage |
|---|---|---|
| Yes | 213 | 51.7 |
| No | 103 | 25.0 |
| Unsure | 96 | 23.3 |
| **Total** | **412** | **100** |

**Source:** Author's computation using SPSS

The table 7 below shows results for the most effective technological tool for adverse effects monitoring system. The most preferred technology for the monitoring of adverse effects, according to the survey, is mobile applications as supported by 48.4% of respondents, followed by artificial intelligence, with 19.2% acceptance, with blockchain applications receiving 18.3% acceptance and big data analytics receiving only 14.1%. These results demonstrate a clear preference for mobile-based solutions, likely due to their accessibility and ease of use for both healthcare providers and the general public. Hence, this indicates the possibility of an ideal system: mobile platforms as a frontline reporting tool with backend support from these more sophisticated technologies for data analysis and security. Based on Olena et al.'s research titled Digital Technology Applications in the Management of Adverse Drug Reactions confirms that digital technologies are transformative across the ADR management lifecycle. Mobile applications serve as frontline tools for accessible reporting, aligning with their high preference in surveys. This is backed by technologies such as: AI which enables toxicity prediction and adverse drug reaction (ADR) signal detection, blockchain which also ensures pharmacovigilance data integrity, and big data which facilitates scalable analysis of EHRs and scientific databases. All of which aligns with this review findings.

**Table 7.** Most effective technology for adverse effects monitoring

| Variable | Frequency | Percentage |
|---|---|---|
| Mobile app | 103 | 48.4 |
| Artificial intelligence | 41 | 19.2 |
| Blockchain | 39 | 18.3 |
| Big Data | 30 | 14.1 |
| **Total** | **412** | **100** |

**Source:** Author's computation using SPSS


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## CONCLUSION

Improvements to Nigeria's vaccine safety monitoring system need to be on urgent grounds to address critical gaps in efficiency, data quality, and public trust. The existing mixed (paper-digital) reporting system captures basic data on adverse events and vaccines but has major drawbacks of underreporting, unstandardized interim tracking, and limited real-time analysis due to technological and infrastructural constraints. Ideally, a more robust structure should encompass mobile technology concepts such as real-time reporting by Artificial Intelligence and blockchain for greater analytical capability and data security, along with big data solutions to really drive causality assessments, while still maintaining a fair balance with traditional systems to ensure inclusivity. Nevertheless, the still-surging issues surrounding difficult reporting processes, resource limitations, and public distrust remain challenges that must be overcome for the most effective maximization of the system. Aspects of success would also require joint investments in training health workers, educating the public, and efficiently interfacing it with other systems so that there is a greater level of confidence and greater usability as far as vaccine safety monitoring is concerned in the country.

Based on the conclusion, the study recommends the following;

i. user-friendly reporting apps should be implemented to improve real-time adverse event documentation and address critical gaps in temporal tracking.
ii. there should be an expanded training for health workers and public awareness to improve reporting quality and participation.
iii. artificial Intelligence for signal detection and blockchain for secure, transparent data management to boost public trust should be integrated.

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