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Pharmacovigilance in the Age of Artificial Intelligence: A Theoretical Account of Signal Detection, Real-World Data and Drug Safety Surveillance in Under-Reporting Environments

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ABSTRACT

Drug-safety surveillance depends on reports of adverse reactions, and most African health systems generate such reports rarely and late. A safety signal that would be detected within months in a high-income country may take years to emerge in these settings, or may never emerge at all. Artificial intelligence (AI) offers to detect signals from other sources, such as electronic health records, social media, pharmacy and insurance data and clinical text, and to triage reports faster. This theoretical paper develops an account of what AI can contribute to pharmacovigilance where the reporting base is thin. It draws on pharmacoepidemiology and regulatory science, on the literature on pharmacovigilance systems, and on recent research on machine learning and natural language processing for adverse-event detection and signal management. The analysis separates three functions that pharmacovigilance must perform: generating reports, where the data do not exist; detecting signals, where the data exist but the pattern is hidden; and acting on signals, where the pattern is found but the regulator does not respond. AI addresses the second function well, the first only where alternative data sources exist, and the third not at all. On this basis the paper advances a set of propositions concerning the data sources and methods suited to under-reporting environments, the risk of false signals from unrepresentative digital data, and the regulatory capacity needed to make AI-enabled surveillance consequential. Nigeria's pharmacovigilance system anchors the analysis, and substandard and falsified medicines are considered as a surveillance problem that AI may help address. The paper concludes that detection improved by artificial intelligence becomes consequential only where the regulatory capacity to investigate and act on signals already exists, so that investment in that capacity is a precondition for, rather than a complement to, investment in AI tools.

Keywords: pharmacovigilance; drug safety; adverse drug reactions; signal detection; artificial intelligence

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1. INTRODUCTION

No medicine is fully characterised when it is approved. Clinical trials enrol limited numbers of carefully selected patients for limited periods, and rare, delayed or population-specific adverse reactions often emerge only after a medicine is used widely. Pharmacovigilance is the science and practice of detecting, assessing, understanding and preventing such adverse effects after approval. Its foundation in most countries is spontaneous reporting: health professionals, and increasingly patients, report suspected adverse reactions to a national centre, which analyses them and contributes them to global databases. Patterns in these reports generate signals, hypotheses that a medicine may cause a particular harm, which are then investigated and, if confirmed, acted on through label changes, restrictions or withdrawals.

Spontaneous reporting depends on reporting, and reporting is uneven. In many African health systems few reports are submitted, reporting is concentrated in a few institutions or programmes, and the populations who use medicines most are underrepresented in the data. Reviews of adverse-drug-reaction reporting by health providers in sub-Saharan Africa identify persistent barriers such as limited awareness, lack of feedback, fear of blame, workload and inadequate reporting tools (Moyo et al., 2023). Reviews of drug-safety systems in Africa document progress in establishing national pharmacovigilance centres alongside continuing limitations in resources and functionality (Ndagije et al., 2023). The consequence is that signals which would be detected quickly where reporting is dense may be detected slowly, or not at all, where it is sparse.

Artificial intelligence promises to change this. Natural language processing can extract adverse events from clinical notes and electronic health records (Golder et al., 2025), social-media analysis can identify adverse events that patients describe online (Golder et al., 2024; Oyebode & Orji, 2023), machine learning can predict adverse drug events from observational health data (Denck et al., 2023; Hu et al., 2024), large language models can automate parts of evidence generation (Painter et al., 2025), and text-mining tools can proactively identify cases in electronic health records to strengthen signal detection (von Kreijfelt et al., 2026). These methods are being developed mainly in data-rich health systems. Their value in under-reporting environments depends on whether the data they require exist there and on whether the systems that must act on their outputs can do so.

This paper develops a framework for assessing that value. It is theoretical rather than empirical. It integrates recent research on pharmacovigilance systems in Africa and in low- and middle-income countries (de Oliveira et al., 2025; Menang et al., 2023, 2025; Moyo et al., 2023; Ndagije et al., 2023; Sankar et al., 2025), on AI and natural language processing for adverse-event detection (Denck et al., 2023; Golder et al., 2024, 2025; Hu et al., 2024; Oyebode & Orji, 2023; Painter et al., 2025; von Kreijfelt et al., 2026), on the methodology of signal detection (Noguchi et al., 2025; Uesawa, 2026), on the governance of AI in pharmacovigilance (Dut, 2026), and on substandard and falsified medicines (Chabalenge et al., 2025; Winkler Martinez et al., 2026). The argument proceeds from an account of the reporting base to an analysis of the distinct functions pharmacovigilance performs, the alternative data sources on which AI depends and the distortions they introduce, the particular case of substandard and falsified medicines, and the question of regulatory capacity, before applying the framework to Nigeria.

2. LITERATURE REVIEW

2.1 The Reporting Base

Spontaneous reporting systems collect individual case safety reports: descriptions of a patient, a suspected medicine and an adverse event. The reports are pooled nationally and globally, most prominently in the World Health Organization's global database, VigiBase. Signals are typically detected by disproportionality analysis, which compares how often an event is reported with a particular medicine to how often it is reported with other medicines. A disproportionately high ratio suggests a possible association that warrants investigation.

Disproportionality analysis has well-known limitations even where reporting is abundant. Spontaneous reports are not a random sample of adverse events; their numbers depend on the awareness of reporters, the novelty of the medicine, publicity and the ease of reporting, and the

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denominator, the number of patients exposed, is unknown. Methodological work continues to examine what the method can and cannot show, including whether it can establish that adverse events are dose-dependent (Noguchi et al., 2025) and how positive and inverse disproportionality signals should be interpreted (Uesawa, 2026). These limitations are amplified where reporting is sparse. With few reports, disproportionality statistics are unstable, real signals are masked by noise, and the reports that do exist may reflect the particular programmes and institutions that submit them rather than the population's experience.

In many African countries the reporting base is thin. Reporting by health providers is hindered by limited training, lack of feedback, workload, uncertainty about what to report and inadequate tools (Moyo et al., 2023). National pharmacovigilance centres exist in most countries, but many lack the staff, funding and legal mandate to function fully (Ndagije et al., 2023). Reviews of strategies to strengthen pharmacovigilance in low- and middle-income countries identify organisational inefficiency, weak infrastructure, inconsistently enforced regulation and inadequate funding as persistent challenges (Menang et al., 2023), and comparative analysis of pharmacovigilance development across income groups shows that few systems in such countries are fully functional (Menang et al., 2025).

Digital reporting tools have been introduced to address some of these barriers. A qualitative study of the Med Safety mobile application in Uganda shows that health workers value the convenience of mobile reporting, but that uptake is shaped by connectivity, awareness, feedback and integration with workflows (Kiguba et al., 2023). Such tools lower the cost of reporting without changing the underlying incentives and capacities that determine whether reports are made at all.

2.2 The Distinct Functions of Pharmacovigilance

It is useful to separate the work of pharmacovigilance into three functions, because AI relates to each of them differently. The first is the generation of the data from which signals can be detected. In under-reporting environments this is frequently the binding constraint: adverse events occur, but they are not recorded in a form the pharmacovigilance system can use. AI can help with this only indirectly, since it cannot create reports of events that are never recorded anywhere. What it can do is extract adverse events from other records where these exist. Clinical notes and electronic health records contain descriptions of adverse events that are never formally reported, and natural language processing can identify them (Golder et al., 2025; von Kreijfelt et al., 2026); patients describe adverse experiences on social media and review sites, and these can be mined (Golder et al., 2024; Oyebode & Orji, 2023). In this sense AI converts existing but unreported data into pharmacovigilance data. The value of that conversion depends on whether such records exist. Where electronic health records are widespread and clinical notes are digital, the pool of unreported adverse events available for extraction is large; where records are mostly on paper, fragmented across facilities or absent, the pool is small. Where social-media use is concentrated among younger, urban and wealthier groups, digital patient reports represent those groups disproportionately. AI therefore addresses the generation problem only to the extent that alternative digital data sources exist, and only for the populations they represent.

The second function is the detection of signals in the data that do exist, and here AI's contribution is strongest. Machine-learning and natural-language-processing methods can process large volumes of reports and records, code free-text descriptions into standard terminologies, identify duplicate reports, triage cases by seriousness and detect patterns that conventional disproportionality analysis would miss. Reviews document a growing body of methods for predicting and detecting adverse drug events from electronic health records and observational data (Denck et al., 2023; Golder et al., 2025; Hu et al., 2024), and large language models can generate structured queries against pharmacovigilance databases from natural-language questions, making evidence generation faster and more accessible (Painter et al., 2025). Detection is the function for which data-rich and data-poor settings differ least in AI's potential, because detection methods can be applied to whatever data exist. Even so, sparse data limit what can be detected: sophisticated methods cannot extract reliable signals from very few reports, and the risk of spurious signals rises as data become thinner.

The third function is acting on signals once they have been detected, which involves investigating them, assessing causality, deciding on regulatory action, communicating risks and changing practice. Action requires regulators with the authority, expertise and resources to evaluate evidence and

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make decisions, and health systems able to implement them. AI does not address this function. A signal detected by an advanced algorithm is of no consequence if the regulator lacks the capacity to investigate it or the authority to act, and in many under-resourced settings this, rather than detection, is the critical gap. Pharmacovigilance systems that are not fully functional (Menang et al., 2025; Ndagije et al., 2023) will not become functional merely because their signal-detection tools improve.

The asymmetry across the three functions mirrors that found in other applications of AI to weak institutional systems. AI is strongest where the problem is computational, as in detection; weaker where the problem is the absence of data, as in generation; and absent where the problem is institutional, as in action. In under-reporting environments it is generation and action, not detection, that typically bind.

2.3 Alternative Data Sources and the Risk of False Signals

The promise of AI-enabled pharmacovigilance in under-reporting environments rests largely on alternative data: electronic health records, social media, pharmacy dispensing records, insurance claims and other digital traces of medicine use and its effects. Each source has strengths, and each carries a specific risk of distortion.

Electronic health records offer clinical detail and a denominator of patients exposed. Natural language processing of clinical notes can identify adverse events with useful accuracy (Golder et al., 2025), and proactive case identification can strengthen signal detection (von Kreijfelt et al., 2026), while machine-learning prediction of adverse events from such records has been assessed systematically, with variable performance across studies and settings (Hu et al., 2024). The limitation in many African settings is coverage: where electronic records exist only in some hospitals, typically urban tertiary and private facilities, the patients they describe are not representative of the population that uses medicines.

Social media offers patient perspectives and rapid availability. A scoping review suggests that social-media analysis can detect adverse events, including events not captured by formal reporting, but that its value varies by platform, medicine and method, and that it supplements rather than replaces conventional pharmacovigilance (Golder et al., 2024); natural language processing of patient reviews can likewise identify adverse reactions that patients report online (Oyebode & Orji, 2023). The limitations here are representativeness and validity. Social-media users are not representative of medicine users, posts are often ambiguous about causality, and digital discourse can be distorted by publicity, misinformation and coordinated campaigns.

A specific risk arises when alternative data are used in under-reporting environments: the risk of false signals, and of missed signals, from unrepresentative data. When formal reporting is sparse, alternative data may dominate the evidence base, and if those data overrepresent particular groups, such as urban, wealthier, digitally connected patients or users of particular facilities, signals will reflect those groups' experience. Adverse events that occur mainly among rural, poorer or less connected populations may be missed, while events whose online discussion is amplified by publicity may generate signals out of proportion to their incidence. Vaccine-safety surveillance is particularly vulnerable to such distortion, because public concern can generate waves of reports and online discussion unrelated to true incidence; experience with vaccine-safety surveillance in South Africa during COVID-19 shows how surveillance systems had to be strengthened rapidly to distinguish real signals from noise (Sankar et al., 2025).

The appropriate response is triangulation. Signals from alternative data should be treated as hypotheses to be tested against other sources, including formal reports, active surveillance and targeted studies, rather than as findings. Active surveillance, in which defined populations are followed systematically for adverse events, can provide the representative data that spontaneous and digital sources lack, but it requires resources and expertise that are scarce in low- and middle-income countries (de Oliveira et al., 2025).

2.4 Substandard and Falsified Medicines as a Surveillance Problem

In many African countries, some apparent adverse events and treatment failures may arise not from the pharmacology of genuine medicines but from substandard and falsified products. Substandard medicines fail to meet quality specifications; falsified medicines deliberately misrepresent their identity or source. Both can cause harm directly, through toxic contaminants or wrong ingredients, and indirectly, through treatment failure and the promotion of antimicrobial resistance. A review of

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substandard and falsified medicines in Africa identifies health-system challenges, supply-chain weaknesses and regulatory limitations as drivers, and calls for strategies to improve access to quality medicines (Chabalenge et al., 2025).

Substandard and falsified medicines can be understood as a surveillance problem in which AI may help, though again unevenly across the three functions. In the generation of data, portable and handheld spectroscopic devices allow medicines to be screened in the field; vibrational spectroscopy using handheld and portable devices and multispectral and hyperspectral imaging have been reviewed as tools for identifying substandard and falsified drugs (Winkler Martinez et al., 2026), and machine-learning analysis of spectral data can classify products as genuine or suspect. In detection, AI can combine data on product quality, adverse-event reports and treatment failures to identify clusters suggesting a quality problem in a particular batch, supplier or region. In action, the familiar constraint reappears: detecting a suspect product is of value only if regulators can trace it, remove it from the market and act against those responsible.

Integrating quality surveillance with pharmacovigilance is a distinctive need in under-reporting environments. In high-income systems, where supply chains are tightly regulated, adverse events can usually be attributed to the pharmacology of the medicine. Where substandard and falsified products circulate widely, an apparent signal may instead reflect a quality problem, and the appropriate regulatory response differs accordingly. AI-enabled surveillance that integrates quality data with adverse-event data could help distinguish the two, but only if the data on product quality are systematically collected.

2.5 Regulatory Capacity

The central claim of the framework is that the binding constraint on pharmacovigilance in many under-reporting environments is not detection but action, and that AI does not relax it. This places regulatory capacity at the centre of any assessment of AI-enabled pharmacovigilance.

Regulatory capacity has several components. A legal mandate gives the regulator authority to require reporting, investigate signals and take action; expertise allows it to evaluate evidence and assess causality; resources fund staff, systems and investigations; independence allows decisions to be made on the evidence rather than under commercial or political pressure; and integration with the health system allows decisions to change practice. Comparative analysis shows that building functional and sustainable pharmacovigilance systems requires all of these, and that their development has been uneven across countries of different income levels (Menang et al., 2025).

AI may widen rather than narrow gaps in regulatory capacity. Dut (2026) argues that gaps in pharmaceutical governance could widen with the adoption of AI, even as AI promises better pharmacovigilance in low-income countries, because advanced regulatory systems are integrating AI into their operations while low-income countries with underdeveloped regulatory capabilities lag behind. The danger is a two-tier global pharmacovigilance system in which AI-enhanced regulators detect and act on signals rapidly, while regulators lacking capacity can neither use AI effectively nor act on the signals others detect.

This danger can be partly mitigated by regional and global cooperation. Signals detected in global databases or by well-resourced regulators can inform action elsewhere, provided that regulators in under-reporting environments have the capacity to evaluate whether signals from other populations apply to their own. AI tools developed for well-resourced systems can be shared, but their outputs must be interpreted by local experts who understand local populations, prescribing practices and supply chains. Investment in regulatory capacity, and particularly in the expertise to evaluate and act on signals, is therefore a precondition for AI to strengthen pharmacovigilance in under-reporting environments.

3. CONCEPTUAL FRAMEWORK

The preceding analysis supports several propositions, stated here as conditional claims open to empirical test and as principles for regulatory policy. The first and most general is that in under-reporting environments the binding constraints on pharmacovigilance are the generation of reports and the capacity to act on signals, not the detection of signals in existing data; because AI strengthens detection most, it addresses the binding constraints least (Menang et al., 2025; Moyo et al., 2023; Ndagije et al., 2023). It follows that AI can address the generation problem only where alternative digital data sources, such as electronic health records and social media, exist, and only for the

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populations those sources represent (Golder et al., 2024, 2025).

The reliance on alternative data carries its own hazard. Where formal reporting is sparse and alternative digital data dominate the evidence base, signals will be biased towards the experience of digitally connected, urban and wealthier populations, and adverse events concentrated in other populations will be systematically missed (Golder et al., 2024; Hu et al., 2024). For this reason, signals derived from alternative data in under-reporting environments should be treated as hypotheses requiring triangulation against formal reports, active surveillance or targeted studies, rather than as findings (de Oliveira et al., 2025; Sankar et al., 2025). A related principle applies to product quality: where substandard and falsified medicines circulate widely, pharmacovigilance must integrate product-quality surveillance with adverse-event surveillance, or quality-related harms will be misattributed to the pharmacology of genuine medicines (Chabalenge et al., 2025; Winkler Martinez et al., 2026).

The final propositions concern governance. The adoption of AI by well-resourced regulators without corresponding investment in under-resourced ones will widen global gaps in pharmacovigilance capacity, producing a two-tier system of drug-safety surveillance (Dut, 2026). AI-enabled pharmacovigilance will therefore be consequential in under-reporting environments only where regulators have the mandate, expertise, resources and independence to investigate and act on signals, which makes investment in these capacities a precondition for, rather than a complement to, investment in AI tools (Dut, 2026; Menang et al., 2023, 2025).

4. ANALYSIS AND DISCUSSION

4.1 Nigeria as an Anchoring Case

Nigeria illustrates the three functions and their constraints. The country has an established national pharmacovigilance system under its medicines regulator, the National Agency for Food and Drug Administration and Control, with a national pharmacovigilance centre that contributes reports to the global database. Yet the challenges documented for sub-Saharan Africa generally apply: limited reporting by health providers, concentration of reports in particular programmes and institutions, and constraints on investigating and acting on signals (Moyo et al., 2023; Ndagije et al., 2023).

The generation of data in Nigeria is shaped by the structure of the health system. Much care is delivered in primary facilities, private clinics, pharmacies and patent medicine stores, where formal reporting is rare. Large public-health programmes, such as those for HIV, tuberculosis, malaria and immunisation, are better placed to generate reports because they have dedicated reporting structures; analysis of adverse events following immunisation with the novel oral polio vaccine type 2 using individual case safety reports in VigiBase illustrates how programme-based reporting can support safety assessment of products used in mass campaigns (Ogar et al., 2026). Medicines used outside such programmes, including many purchased directly from pharmacies and medicine vendors, are poorly covered.

The alternative data available for AI-enabled pharmacovigilance in Nigeria are limited and unevenly distributed. Electronic health records are used in some tertiary, private and programme facilities but are far from universal, and social-media use, though substantial and growing, is concentrated among younger, urban and more educated Nigerians. The warning about unrepresentative data therefore applies with particular force. Signals generated from Nigerian digital data will reflect the experience of these groups and may miss adverse events among rural, older and poorer populations who use medicines heavily but are least represented online.

The problem of substandard and falsified medicines is also salient, with supply-chain weaknesses and regulatory challenges that allow poor-quality products to circulate (Chabalenge et al., 2025). An AI-enabled surveillance system for Nigeria should therefore integrate product-quality data, including field screening with portable devices (Winkler Martinez et al., 2026), with adverse-event and treatment-failure data, so that quality problems can be distinguished from intrinsic drug effects.

The capacity to act is the most consequential constraint. Nigeria's regulator has a broad mandate covering foods, drugs, cosmetics and other products, and its pharmacovigilance function competes for resources with registration, inspection and enforcement. For AI-enabled surveillance to change drug-safety outcomes, that function needs the expertise to evaluate signals, the resources to investigate them, and the authority and independence to act. Regional cooperation, including through continental regulatory

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harmonisation, could allow Nigeria to draw on signals detected elsewhere while contributing its own, but that too requires local capacity to judge whether external signals apply to Nigerian patients.

4.2 Implications

For pharmacovigilance practitioners in under-reporting environments, the framework implies that AI tools should be deployed first where they address the binding constraints. Tools that make reporting easier and that extract adverse events from existing clinical records address the generation of data (Golder et al., 2025; Kiguba et al., 2023), tools that triage and code reports address detection, and signals from alternative data should be triangulated rather than accepted at face value (de Oliveira et al., 2025). For regulators and governments, the more fundamental implication is that investment in regulatory capacity must precede or accompany investment in AI tools: the expertise to evaluate signals, the resources to investigate them, a clear legal mandate and the independence to act are the conditions under which AI-enabled surveillance becomes consequential (Dut, 2026; Menang et al., 2025), and integrating product-quality surveillance with pharmacovigilance is a distinctive priority where substandard and falsified medicines circulate (Chabalenge et al., 2025).

For those who develop AI pharmacovigilance tools, the analysis highlights the need to design for representativeness. Tools should report the populations their data represent and should flag signals that may reflect data composition rather than drug effects, and tools developed in data-rich settings should be validated in the settings where they will be used before their outputs inform regulatory action. For global health partners, the risk of a two-tier pharmacovigilance system (Dut, 2026) should be addressed directly: sharing AI tools is insufficient, and what is needed is investment in the capacity of under-resourced regulators to use them and to act on what they reveal, together with global data-sharing arrangements that allow signals detected anywhere to inform action everywhere.

The propositions also identify open questions for research. How representative are alternative digital data sources in African settings, and how large are the resulting biases in signal detection? How accurately can AI extract adverse events from the clinical records available in African facilities? How can product-quality and adverse-event surveillance be integrated in practice, and which components of regulatory capacity most limit the consequences of signal detection? Answering these questions requires research conducted in African health systems rather than extrapolation from data-rich ones.

5. CONCLUSION AND RECOMMENDATION

Pharmacovigilance depends on data, and in many African health systems the data are thin. Artificial intelligence offers powerful tools for detecting signals in data that exist and for extracting adverse events from records that were never formally reported, but these tools address the problems of under-reporting environments unevenly. They strengthen detection substantially; they help with the generation of data only where alternative digital sources exist and only for the populations those sources represent; and they do not address the capacity to act on signals, which is often the binding constraint.

Two dangers follow. The first is false confidence, as signals derived from unrepresentative digital data are mistaken for evidence about the whole population while adverse events among the least connected go undetected. The second is divergence, as well-resourced regulators that adopt AI detect and act on signals faster while under-resourced regulators fall further behind. Both dangers can be mitigated, by triangulating signals, designing tools for representativeness, integrating quality surveillance and, above all, investing in regulatory capacity.

For Nigeria and other countries where reporting is thin and substandard and falsified medicines circulate, the path to safer medicines runs through institutions as much as algorithms. AI can help find the signals hidden in the data; ensuring that those signals reach a regulator able and willing to act, and that the data represent all the people who use medicines, remains a task of public health and governance.

6. CONTRIBUTION TO EXISTING KNOWLEDGE

The paper contributes a separation of the functions pharmacovigilance must perform, generating reports, detecting signals and acting on them, and shows that artificial intelligence strengthens detection most and addresses the binding constraints of under-reporting environments least.

It gives regulators and health systems a basis for investing in the generation of data and the capacity

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to act on signals, and for integrating product-quality surveillance with adverse-event surveillance where substandard and falsified medicines circulate, rather than treating improved signal detection as sufficient on its own.

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