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The Influence of Community Cultural Practices on the Quality of Indigenous Medicine in Kajiado and Tharaka Nithi Counties, Kenya

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Abstract The growing reliance on indigenous medicine in Kenya has intensified concerns regarding its safety, consistency, and quality. Pharmacovigilance surveillance systems are central to monitoring adverse drug reactions and ensuring quality assurance; however, their effectiveness within indigenous medicine systems remains inadequately understood. This study examined the influence of surveillance systems on the quality of indigenous medicine in Kajiado and Tharaka Nithi Counties, Kenya. Anchored on Regulatory Compliance Theory and the Health Belief Model, the study adopted a mixed-methods research design. Quantitative data were collected from 334 respondents across regulators, community health promoters, practitioners, and manufacturers/suppliers, while qualitative data were obtained through key informant interviews. Descriptive statistics and binary logistic regression were used for quantitative analysis, while qualitative data were analysed thematically. The findings reveal that functional surveillance systems significantly increase the likelihood of good-quality indigenous medicine (OR = 2.37, p = .002). However, descriptive and qualitative evidence indicates that these systems are constrained by weak reporting mechanisms, unclear reporting channels, limited feedback loops, and poor stakeholder integration. The study concludes that while surveillance systems have strong potential to improve medicine quality, their operational effectiveness remains limited. Strengthening reporting infrastructure, enhancing feedback systems, and improving system integration are essential for improving the safety and quality of indigenous medicine in Kenya.

Keywords Pharmacovigilance, Surveillance Systems, Indigenous Medicine, Quality, Adverse Drug Reactions, Kenya, Health Systems Strengthening

1. Introduction

Indigenous medicine remains a cornerstone of healthcare delivery in many low- and middle-income countries, particularly in sub-Saharan Africa, where it serves as a primary source of treatment for a large proportion of the population. The World Health Organization estimates that nearly 80% of people in developing countries rely on traditional or indigenous medicine for their primary healthcare needs [1,2]. This reliance is driven by a combination of structural and socio-cultural factors, including limited access to formal healthcare services, affordability constraints, and deeply rooted cultural beliefs that shape health-seeking behaviour. In Kenya, the use of indigenous medicine is similarly widespread, with over 70% of the population utilizing these services due to their accessibility, perceived effectiveness, and alignment with local cultural practices [1,3]. As such, indigenous medicine constitutes a critical but largely informal component of the national health system.

Despite its widespread use, concerns about the safety, consistency, and quality of indigenous medicine persist. Unlike conventional pharmaceutical products, which undergo rigorous regulatory approval, standardized manufacturing, and clinical validation, indigenous medicines are often prepared using informal and highly variable processes. This variability introduces risks related to inconsistent dosing, contamination, and uncertain efficacy. These concerns are widely documented in the literature on herbal and traditional medicines [4]. Empirical studies highlight recurring challenges, including variability in active ingredients, lack of quality control, and undocumented adverse drug reactions [5,6]. Weak regulatory oversight and limited integration into formal health systems further compound these risks, creating gaps in accountability and quality assurance [3].

Pharmacovigilance surveillance systems provide a critical mechanism for addressing these challenges. These systems enable the systematic detection, reporting, analysis, and prevention of adverse drug reactions, thereby generating evidence necessary for improving medicine safety and

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quality [1,7]. Their relevance is particularly pronounced in indigenous medicine contexts, where variability in preparation and use is high. By linking patient experiences, practitioner practices, and regulatory oversight, surveillance systems support more responsive, data-driven decision-making and continuous quality improvement [5].

However, in Kenya and similar low-resource settings, pharmacovigilance systems for indigenous medicine remain underdeveloped and fragmented. Reporting pathways are often unclear or poorly understood, and many practitioners and community-level actors lack both awareness and incentives to report adverse events. This aligns with broader evidence showing that weak reporting culture and lack of incentives significantly undermine pharmacovigilance systems [8]. Feedback mechanisms, which are essential for reinforcing reporting behaviour and enabling system learning, are frequently weak or absent. In addition, coordination among key stakeholders, including regulators, healthcare providers, indigenous practitioners, and community health actors, remains limited. These structural and operational constraints contribute to significant underreporting and hinder the generation of reliable safety data needed for timely regulatory action [3,5].

These challenges are particularly evident in Kajiado and Tharaka Nithi Counties, where indigenous medicine is widely practiced and deeply embedded in community health systems. The largely informal nature of practice, combined with limited regulatory oversight and weak surveillance infrastructure, results in fragmented and inconsistent safety monitoring. From a systems perspective, such fragmentation reflects broader weaknesses in health system integration and governance [9]. Adverse drug reactions are often managed at the household or practitioner level without formal documentation or escalation to regulatory authorities, raising concerns about the effectiveness of existing systems in safeguarding public health.

Although pharmacovigilance has been extensively studied in relation to conventional pharmaceutical systems, its application within indigenous medicine contexts remains insufficiently understood, particularly in Kenya. Existing frameworks are often not adequately adapted to the unique characteristics of indigenous medicine, resulting in gaps in monitoring, reporting, and quality assurance. This lack of context-specific evidence limits the ability of policymakers and regulators to design effective interventions for strengthening surveillance systems in indigenous medicine settings.

This study therefore examines the influence of pharmacovigilance surveillance systems on the quality of indigenous medicine in Kajiado and Tharaka Nithi Counties, Kenya. By integrating quantitative and qualitative evidence, the study provides a comprehensive assessment of the operational effectiveness of these systems and their role in shaping medicine quality outcomes. The findings aim to inform policy, strengthen regulatory frameworks, and support the integration of indigenous medicine into broader health system quality assurance efforts.

2. Methodology

This study employed a convergent mixed-methods design, allowing for the simultaneous collection and integration of quantitative and qualitative data to provide a more nuanced understanding of how surveillance systems influence the quality of indigenous medicine. This approach enabled triangulation of findings and strengthened the validity and interpretability of results.

Study setting

The study was conducted in Kajiado and Tharaka Nithi Counties, Kenya, regions where indigenous medicine remains widely utilized alongside formal healthcare systems. These counties were purposively selected due to their active engagement in indigenous medicine practices, diversity of stakeholders, and ongoing policy interest in strengthening regulatory and surveillance frameworks.

Study population and sampling

The study targeted key stakeholders involved in the indigenous medicine ecosystem, including regulators, community health promoters, traditional medicine practitioners, and manufacturers /suppliers. A stratified random sampling approach was used to ensure proportional representation across these stakeholder groups. Within each stratum, respondents were randomly selected from available stakeholder lists provided by county health departments and relevant professional associations. The final sample comprised 334 respondents for the quantitative component. For the qualitative component, key informant interviews (KIIs) were conducted with purposively selected participants based on their expertise and role in surveillance and regulatory processes, ensuring depth of insight.

Data collection

Quantitative data were collected using a structured questionnaire administered through trained research assistants. The tool captured key dimensions of surveillance systems, including: reporting mechanisms for adverse events, feedback and response systems, and stakeholder coordination and integration. Qualitative data were obtained through semi-structured key informant interviews, guided by an interview protocol designed to explore experiences, perceptions, and systemic challenges related to pharmacovigilance and quality assurance in indigenous medicine.

Measurement of variables

The dependent variable was the quality of indigenous medicine, operationalized as a binary outcome (good vs. poor quality) based on predefined criteria including safety, consistency, and adherence to recommended practices. The main independent variable, surveillance system adequacy, was similarly categorized (adequate vs. inadequate) based on composite indicators derived from reporting efficiency, feedback mechanisms, and stakeholder engagement.

Data quality assurance

To enhance reliability and validity, the data collection

instruments underwent pre-testing in a comparable setting. Feedback from the pre-test informed refinement of the tools. Internal consistency of scales was assessed using Cronbach's alpha, while content and face validity were ensured through expert review by specialists in public health, pharmacovigilance, and health systems research. Research assistants received standardized training to ensure consistency in data collection procedures.

Data analysis

Quantitative data were analysed using SPSS version 26. Descriptive statistics (frequencies, proportions, means) were used to summarize respondent characteristics and key variables. A binary logistic regression model was employed to estimate the association between surveillance system adequacy and the likelihood of achieving good-quality indigenous medicine. Adjusted odds ratios (AORs) with 95% confidence intervals (CIs) were reported, and statistical significance was set at $p < 0.05$. Model diagnostics, including goodness-of-fit tests and multicollinearity checks, were performed to ensure robustness.

Qualitative data were transcribed verbatim and analysed using thematic analysis. An inductive coding approach was applied, involving open coding, development of categories, and identification of emerging themes. Findings were then integrated with quantitative results during interpretation to provide a comprehensive explanation of observed patterns.

Ethical considerations

Ethical approval was obtained from a recognized Kenya Methodist University Science, Ethics and Research Committee (SERC) and a research permit was obtained from the National Commission for Science, Technology and Innovation (NACOSTI), Kenya. Permission to conduct the study was also obtained from relevant county authorities. All participants provided written informed consent prior to participation. Confidentiality was maintained through anonymization of data, and participation was entirely voluntary, with the right to withdraw at any stage without penalty.

3. Results

The descriptive findings in Table 1 show a fairly weak and underperforming pharmacovigilance surveillance systems, particularly in relation to the reporting and follow-up of adverse drug reactions (ADRs).

More than half of the respondents expressed disagreement with statements describing the presence and effectiveness of core pharmacovigilance structures. Specifically, 50.3% of respondents indicated that there are no clear systems for reporting ADRs, while (54.5%) disagreed that ADRs are consistently reported. Similarly, 52.7% reported a lack of well-defined reporting channels, and 56.9% indicated that feedback is not provided after reporting adverse reactions. These findings are reflected in the relatively low mean scores for these items (ranging from 2.58 to 2.71 on the scale), suggesting a general perception that pharmacovigilance systems are poorly implemented. The standard deviations (approximately 1.05–1.11) indicate moderate variability in responses, but not enough to obscure the dominant trend of dissatisfaction.

These results point to systemic gaps in the pharmacovigilance infrastructure, particularly in three areas namely, clarity of reporting systems, consistency of ADR reporting, and feedback mechanisms. The inadequate feedback loop is especially notable, as it may discourage continued reporting and weaken trust in the system.

A slightly higher proportion of respondents (38.9%) with mean score of 3.04, agreed that surveillance systems improve the safety of indigenous medicine. This suggests that despite the evident operational weaknesses, there is a recognition of the potential value and importance of pharmacovigilance systems in enhancing the safety of indigenous medicine.

Table 1. Descriptive Statistics for Pharmacovigilance Surveillance Systems

Item	Disagree n (%)	Neutral n (%)	Agree n (%)	Mean	SD
There are clear systems for reporting adverse drug reactions	168 (50.3)	82 (24.6)	84 (25.1)	2.71	1.08
Adverse drug reactions are consistently reported	182 (54.5)	76 (22.8)	76 (22.7)	2.64	1.05
There are well-defined reporting channels	176 (52.7)	80 (24.0)	78 (23.3)	2.67	1.09
Feedback is provided after reporting adverse reactions	190 (56.9)	74 (22.2)	70 (21.0)	2.58	1.11
Surveillance systems improve the safety of indigenous medicine	118 (35.3)	86 (25.7)	130 (38.9)	3.04	1.12

Note. n = 334. Values are frequencies with percentages in parentheses; Mean and SD denote item-level statistics.

Table 2. Variables in the Equation for Surveillance Systems

Variable	Category	B	S.E.	Wald	df	p-value	Odds Ratio
Surveillance Systems	Inadequate (RC)						1.000
	Adequate	0.864	0.281	9.441	1	.002	2.37

Note. RC = Reference Category.

The findings suggest a disconnect between perceived potential and actual performance. While respondents appear to believe in the role of surveillance systems in improving safety, their day-to-day experiences indicate that these systems are not functioning effectively. This gap underscores the need for strengthening system design, improving reporting structures, ensuring consistent implementation, and establishing responsive feedback loops to enhance both utilization and trust in pharmacovigilance systems.

This quantitative pattern is strongly reinforced by qualitative evidence, which demonstrates that adverse events associated with indigenous medicine are largely managed through informal, practitioner-centred responses rather than through structured reporting pathways. One participant stated that

"… *when a medicine causes problems, the healer just changes it or tells you to stop, but there is no reporting to anyone else …" (Patient 11).*

Another observed that

"… the practitioner listens but there is no place they report these problems to…" (Patient 14).

These accounts are analytically significant because they reveal that adverse reactions are recognised at the user and practitioner levels, but the transition from experiential knowledge of harm to formal pharmacovigilance action is largely missing, preventing the generation of actionable safety intelligence.

The weakness of feedback mechanisms emerges in the qualitative results as well. The lowest mean score was recorded for provision of feedback after reporting (Mean = 2.58), and qualitative narratives highlight the absence of follow-up and accountability. The following are excerpts from the participants.

"… once the medicine is sold, nobody follows up even if people complain …" (Patient 22).

Another said that

"… the seller just says it has worked for others and there is no reporting beyond that …" (Patient 19).

This indicates that the pharmacovigilance cycle is incomplete, undermining accountability, discouraging reporting behaviour, and limiting system learning. A further implication is weak integration across stakeholders, with problems contained within localised interactions and minimal linkage to formal regulatory systems. This fragmentation restricts information flow and prevents aggregation of incidents into broader safety signals. However, the moderate agreement that surveillance systems can improve safety (Mean = 3.04) indicates conceptual acceptance but operational failure, which underscores a gap between perceived usefulness and institutional functionality.

Table 2 presents the results of a logistic regression analysis examining the effect of pharmacovigilance surveillance systems on quality of indigenous medicine.

Using "inadequate surveillance systems" as the reference category, the findings show that adequate surveillance systems have a positive and statistically significant effect on quality of indigenous medicine. The regression coefficient (B = 0.864) indicates that moving from inadequate to adequate systems increases the log odds of the quality. The odds ratio of 2.37 suggests that communities with adequate surveillance systems are more than twice as likely to achieve the desired quality of indigenous medicine compared to those with inadequate systems. This effect is statistically significant (p = .002), meaning that the observed association is unlikely to be due to chance. The Wald statistic (9.441) further confirms that the predictor contributes meaningfully to the model.

These results reinforce the descriptive findings in that strengthening surveillance systems is not just theoretically important, it has a measurable impact. Adequate pharmacovigilance structures, such as clear reporting mechanisms, consistent ADR reporting, and effective feedback systems, substantially increase the likelihood of improving quality of indigenous medicine. From the findings, it shows that there is strong empirical support for prioritizing investments in surveillance systems, as improvements in this area are associated with significantly better performance in the health system, particularly in the context of indigenous medicine.

This finding is consistent with empirical evidence showing that effective pharmacovigilance systems enhance medicine safety through early detection of adverse drug reactions and improved regulatory oversight [1,3].

This finding is consistent with existing literature which identifies pharmacovigilance systems as critical institutional mechanisms for improving medicine safety and quality. Olsson et al. [5] observed that robust surveillance systems enhance the early detection of safety signals and support timely regulatory intervention, thereby reducing the risk of harm associated with poor-quality medicines. Similarly, the World Health Organization [1] emphasises that effective pharmacovigilance systems strengthen medicine safety by generating actionable evidence for monitoring adverse reactions and guiding regulatory response. Within indigenous medicine contexts, Muriithi et al. [3] found that surveillance practices contribute to improved safety oversight by creating opportunities to identify harmful reactions, unsafe preparation practices, and quality inconsistencies that might otherwise remain undocumented. In the same vein, Dubale et al. [6] argue that surveillance systems strengthen quality assurance by enabling the detection of contamination, dosage irregularities, and other risks associated with weakly regulated medicine environments.

4. Conclusions

The findings demonstrate that pharmacovigilance surveillance systems play a significant and measurable role in improving the quality of indigenous medicine. The logistic regression results show that adequate surveillance systems more than double the likelihood of achieving

good-quality indigenous medicine (OR = 2.37, p = .002), confirming their critical importance as a health system function.

The findings show that the effectiveness of the pharmacovigilance surveillance systems is weak because its full operational performance remains constrained by unclear reporting mechanisms, inconsistent reporting of adverse drug reactions (ADRs), absence of effective feedback loops, and limited coordination among stakeholders. These weaknesses undermine trust, discourage reporting behavior, and prevent the generation of actionable safety data.

Importantly, stakeholders still recognize the value of surveillance systems, suggesting that the issue is not conceptual acceptance but system design and implementation failure. Overall, the study concludes that while pharmacovigilance systems have strong potential to enhance safety and quality, their current effectiveness is constrained by systemic and operational deficiencies, limiting their contribution to health system strengthening.

5. Recommendations

To bridge the gap between potential and performance, the following actions are recommended:

1. **Strengthening Reporting Systems and Infrastructure**
   a. The national government regulator should develop clear, standardized, and user-friendly adverse drug reaction (ADR) reporting mechanisms tailored to indigenous medicine contexts.
   b. Establish functional feedback mechanisms by creating structured feedback loops to ensure that reported cases lead to visible action.
2. **Enhancing Stakeholder Coordination and System Integration**
   a. Promote collaboration among regulators, traditional practitioners, community health promoters, and manufacturers to enhance coordination and information sharing.
   b. Develop integrated systems to improve information flow and facilitate comprehensive safety monitoring across stakeholders.
3. **Capacity Building and Community Engagement**
   a. Train practitioners and community-level actors on pharmacovigilance principles, reporting procedures, and the importance of surveillance systems in improving medicine safety.
   b. Promote community engagement by educating patients and communities on the importance of reporting adverse effects to encourage bottom-up participation in surveillance systems.

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