Project IRIS (Integrated Registry of Indigenous Systems): A Digital Public Health Framework for the Standardisation, Safety, and Integration of Nigerian Herbal Medicinal Products

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ABSTRACT

Traditional herbal medicine (THM) remains a dominant source of healthcare for millions of Nigerians and continues to function as a first-line health system in many communities. Despite its widespread use, the governance of herbal medicinal products (HMPs) in Nigeria is characterised by weak standardisation, limited pharmacovigilance, fragmented evidence generation, and minimal integration with orthodox health systems. These gaps pose significant public health risks, including adverse drug reactions, herb–drug interactions, and regulatory blind spots.

This article presents Project IRIS (Integrated Registry of Indigenous Systems), a digital public health innovation designed to strengthen the safety, regulation, and evidence base of Nigerian HMPs through a unified national informatics platform. Project IRIS integrates three core components: a standardised digital HMP registry, an adapted pharmacovigilance reporting system, and a linked evidence repository. Anchored in health systems strengthening and digital health theory, the project aligns with the World Health Organisation's Traditional Medicine Strategy and emerging global frameworks for data-driven integrative care. This paper provides a comprehensive conceptual, methodological, and technical exposition of Project IRIS and argues that digital integration of traditional medicine is essential for patient safety, regulatory intelligence, and equitable universal health coverage in low- and middle-income countries.

INTRODUCTION

Traditional medicine occupies a paradoxical position in global public health. On one hand, it is one of the most widely utilised health resources globally; on the other, it remains marginalised within formal health governance, surveillance, and data systems (World Health Organisation (WHO, 2019). In Nigeria, traditional herbal medicine (THM) is not merely complementary; it is foundational. Cultural legitimacy, affordability, geographic accessibility, and historical continuity sustain its dominance, particularly among rural populations and urban low-income groups (Abdullahi, 2011).

However, the absence of robust integration mechanisms between traditional and orthodox medicine creates systemic vulnerabilities. Patients frequently engage in medical pluralism, using herbal remedies alongside biomedical treatments without disclosure to healthcare providers. This increases the risk of adverse events, treatment failure, and avoidable morbidity (Ezuruike & Prieto, 2014). From a public health perspective, the lack of structured data on HMP composition, safety, and effectiveness represents a critical blind spot in national health intelligence.

Digital health innovations now provide a transformative opportunity to address these challenges. Rather than attempting to replace or marginalise traditional medicine, digital platforms can serve as bridging infrastructures, enabling documentation, surveillance, and evidence synthesis while respecting indigenous knowledge systems. Project IRIS emerges within this paradigm.

Background and Problem Statement

Traditional Herbal Medicine as a De Facto Health System

In Nigeria, THM operates as a parallel but dominant health system. Traditional medicine practitioners (TMPs) deliver services ranging from primary care to chronic disease management, maternal health support, and mental health interventions. This reality challenges the biomedical assumption that traditional medicine exists at the

periphery of health systems. Instead, THM constitutes a functional but weakly governed subsystem within Nigeria's broader health architecture.

Despite this, national health information systems, disease surveillance platforms, and pharmacovigilance mechanisms almost entirely exclude THM. This exclusion undermines comprehensive health planning and contradicts WHO recommendations for inclusive health systems (WHO, 2014).

Key Systemic Challenges

Lack of Standardisation

Herbal medicinal products often lack consistent botanical identification, dosage formulation, and manufacturing standards. Variability in plant species, harvesting methods, and preparation techniques leads to unpredictable therapeutic outcomes and safety profiles.

Absence of Pharmacovigilance

Unlike orthodox medicines, HMPs are rarely subjected to structured post-market surveillance. Adverse reactions, toxicity, contamination, and herb–drug interactions are significantly underreported, limiting early signal detection and regulatory response.

Fragmented Evidence Ecosystem

Ethnobotanical knowledge, laboratory research, and clinical studies exist in silos. Without aggregation and linkage, evidence remains underutilised in policymaking, clinical guidance, and regulatory review.

Regulatory Gaps

While NAFDAC registers HMPs, registration alone does not ensure continuous safety monitoring, evidence updating, or lifecycle regulation. Static registries are insufficient in a dynamic therapeutic landscape.

Conceptual Foundation of Project IRIS

Theoretical Underpinnings

Project IRIS is grounded in three intersecting theoretical domains:

1. **Health Systems Strengthening Theory** – recognising that resilient health systems require inclusive governance of all care modalities.

2. **Digital Health and Informatics Theory** – leveraging data infrastructures to improve surveillance, decision-making, and accountability.

3. **Integrative Medicine Frameworks** – promoting respectful coexistence and evidence-informed collaboration between traditional and orthodox medicine.

Vision

To transform Nigerian herbal medicinal products from informally governed commodities into digitally documented, safety-monitored, and evidence-linked public health assets.

Conceptual Framework

Description

The Project IRIS conceptual framework positions digital infrastructure as the central enabling mechanism that links traditional medicine practice, regulatory oversight, research generation, and patient safety outcomes.

Conceptual Framework Diagram (Figure 1) 4.1 Phase I: Co-Design and Platform Development

Project IRIS adopts a participatory co-design methodology. This approach recognizes that digital health interventions in culturally sensitive domains require legitimacy, trust, and usability. Stakeholders include regulators, researchers, TMPs, pharmacists, clinicians, and health informaticians.

The Minimum Viable Product (MVP) comprises three interoperable modules:

Module A: Digital Herbal Medicinal Product Registry – serving as the foundational component of the IRIS platform, this module captures comprehensive, standardised, and interoperable data on herbal medicinal products. It includes precise botanical identification using accepted taxonomic nomenclature (genus, species,

plant part used), formulation and dosage forms, manufacturing and sourcing information, intended therapeutic indications, contraindications, precautions, and known or suspected herb–drug interactions. The registry further integrates regulatory metadata such as NAFDAC registration numbers, approval status, and post-market updates, enabling lifecycle tracking of products. By transforming heterogeneous and informal product information into structured digital records, this module establishes a reliable reference point for regulators, healthcare professionals, researchers, and consumers, and underpins subsequent pharmacovigilance and evidence-generation functions of Project IRIS.

Module B: Pharmacovigilance Portal – constituting the safety surveillance backbone of Project IRIS, this module is designed to systematically capture, analyse, and respond to suspected adverse events, toxicity, quality defects, and herb–drug interactions associated with herbal medicinal products. The portal supports multi-channel reporting pathways tailored to different user groups, including simplified consumer-facing mobile and USSD-based reporting, structured web-based forms for healthcare professionals, and dedicated interfaces for traditional medicine practitioners. Reporting templates are adapted from World Health Organization–Uppsala Monitoring Centre (WHO-UMC) pharmacovigilance standards, with additional data fields specific to herbal medicines, such as plant source variability, preparation methods, duration of use, and potential adulteration. By lowering reporting barriers and formally incorporating traditional medicine practitioners into national safety surveillance, this module enables early signal detection, strengthens regulatory oversight, and addresses a critical blind spot in Nigeria's pharmacovigilance system.

Module C: Evidence Dashboard – functioning as the knowledge integration and translational research component of Project IRIS, this module systematically aggregates, curates, and links diverse forms of evidence to specific herbal medicinal products within the digital registry. The dashboard integrates peerreviewed scientific literature (including phytochemical analyses, preclinical studies, and clinical trials), ethnobotanical documentation, policy reports, and anonymised case series generated through the pharmacovigilance module. Evidence is indexed and tagged to individual products using unique IRIS identifiers, enabling users to trace claims of efficacy and safety directly to supporting—or contradictory—data. By presenting complex research outputs through an accessible, searchable interface, the Evidence Dashboard supports regulators in evidence-informed decision-making, assists healthcare professionals in clinical risk–benefit assessment, and promotes responsible use by consumers. Importantly, this module transforms fragmented and largely inaccessible traditional medicine research into a living evidence ecosystem, facilitating continuous learning, research prioritisation, and the gradual elevation of credible herbal medicinal products within the formal health system.

Phase II: Pilot Implementation

The pilot phase is designed to rigorously test the real-world feasibility, acceptability, and operational performance of the IRIS platform across diverse sociocultural and health system settings. Implementation will occur in selected states representing varying levels of urbanisation, health infrastructure, and traditional medicine utilisation. Structured training workshops will be delivered to all participant groups—including traditional medicine practitioners, healthcare professionals, pharmacists, and regulatory staff—focusing on accurate data entry, ethical reporting practices, and

Phase III: Evaluation and Learning

A mixed-methods evaluation framework assesses adoption, usability, data completeness, and perceived impact. Quantitative metrics are complemented by qualitative insights from users and regulators, generating actionable lessons for scale-up.

Methodology and Proof-of-Concept Design

Phase I: Co-Design and Platform Development

A participatory design approach ensures that the system reflects cultural realities and regulatory requirements. Stakeholders co-define data fields, reporting workflows, and ethical safeguards. This approach reduces resistance, impro

Phase II: Pilot Implementation

Pilot testing in two socio-economically diverse states allows assessment of adaptability across contexts. Training focuses not only on system use but also on pharmacovigilance literacy, data ethics, and patient safety culture.

Phase III: Evaluation and Impact Assessment

A mixed-methods evaluation framework assesses:

- **Quantitative indicators:** reporting rates, registry completeness, system usage metrics

- **Qualitative indicators:** user perceptions, trust, and practice change

This aligns with implementation science methodologies for complex health interventions (Peters et al., 2013).

Technical Architecture and Data Governance

Project IRIS employs a cloud-based microservices architecture to ensure scalability and interoperability. HL7 FHIR compatibility enables future integration with national health management information systems (HMIS). Robust encryption, role-based access control, and anonymisation protocols safeguard sensitive data.

Data Governance and Security Flow in Project IRIS

Expected Outcomes and Public Health Impact

Short-Term Outcomes

- Improved documentation of HMPs

- Increased reporting of adverse events

- Enhanced regulatory visibility

Long-Term Impact

- Reduced preventable adverse drug reactions

- Evidence-informed integrative care models

- Strengthened progress toward universal health coverage

Contribution to Knowledge

This study advances public health scholarship by:

- Providing one of the first digital integration frameworks for traditional medicine governance in Africa

- Extending pharmacovigilance theory to herbal medicine contexts

- Demonstrating how indigenous knowledge systems can be modernised without erasure

CONCLUSION

Project IRIS reframes traditional medicine integration as a data governance challenge rather than a cultural dilemma. By centring digital infrastructure, patient safety, and evidence generation, it offers a scalable and ethically grounded model for strengthening health systems in Nigeria and comparable LMICs.

REFERENCES

1. Abdullahi, A. A. (2011). Trends and challenges of traditional medicine in Africa. African Journal of Traditional, Complementary and Alternative Medicines, 8(5), 115–123.
2. Ezuruike, U. F., & Prieto, J. M. (2014). The use of plants in the traditional management of diabetes in Nigeria. Journal of Ethnopharmacology, 155(2), 857–924.
3. Peters, D. H., Adam, T., Alonge, O., Agyepong, I. A., & Tran, N. (2013). Implementation research: What it is and how to do it. BMJ, 347, f6753.
4. World Health Organization. (2014). WHO traditional medicine strategy 2014–2023. WHO Press.
5. World Health Organization. (2019). WHO global report on traditional and complementary medicine. WHO Press.