

Perspective

Evidence-Based Validation of Traditional Medicine in Ethiopia: Challenges and Future Directions

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Abstract

Traditional medicines have huge potential health and economic benefits, with the global traditional medicine currently valued at about US\$ 175 billion. However, due to their natural origin and anecdotal reports, there appears to be a misplaced claim of benefit and safety, which is amplified by social media. In this perspective article, we call for the systematic recording and careful validation of traditional knowledge.

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Background

Traditional medicine plays a significant role in the healthcare systems of many countries, particularly developing countries. In Ethiopia, it is estimated that approximately 60-79% of the population uses traditional medicine (1). Traditional medicine also has a vast economic potential. In 2023, the global traditional medicine market was valued at \$ 174.89 billion and is expected to grow at an annual rate of 7.5%, reaching \$ 289.66 billion by 2030 (2). However, owing to its natural origin and anecdotal reports, the perceived safety and efficacy of traditional medicines seem misplaced. These assumptions have to be tested and validated (3). This perspective examines the barriers to evidence-based validation of traditional medicine in Ethiopia and calls for improved documentation of traditional medicine knowledge, clearer research frameworks, and better coordination efforts.

Challenges to evidence-based validation

Recognizing the significance of traditional medicine, Ethiopia incorporated it into its first national drug policy in 1993. Since then, it has been organized within the Federal Ministry of Health and its various agencies, including the Ethiopian Food and Drug Authority

(EFDA), the Ethiopian Public Health Institute (which has now moved to the Armauer Hansen Research Institute), and Regional Health Bureaus. Ethiopia has also commenced the registration and licensing of traditional medicine practitioners (TMPs). A comprehensive national policy on traditional medicine, alongside multiple directives and guidelines, has also been designed to facilitate its validation, regulation, and integration (3,4,5).

One of the main obstacles to evidence-based validation of traditional medicine is the lack of adequate documentation of indigenous knowledge. Much of Ethiopia's traditional medical knowledge is undocumented and is passed down primarily through oral tradition. Most of the available records have been generated only recently, particularly through ethnobotanical and/or ethnopharmacological studies (4,6). Although these recent attempts have cataloged valuable knowledge about traditional medicine, particularly traditional herbal medicine, they have two fundamental flaws in their approach to ethnomedicine.

The first flaw is the narrow scope of these studies,

mainly focusing on the treatment domain of ethnomedicine, particularly herbal medicines, rather than the holistic perspective of ethnomedicine, which explores and documents a broader understanding of health, illness, the body, and the causes of disease, as well as prevention, diagnosis, and treatment.

The second flaw, which partially stems from the limited scope of the available surveys, is the widespread reporting of traditional medicine claims using modern disease terms without adequately explaining how these terms were mapped from traditional to modern disease diagnoses. Given the complexity of translation between traditional and modern medical systems, the ethnomedical knowledge documented in these studies could potentially be misleading and further complicate the validation of traditional medicine (7). Hence, there is a pressing need for a comprehensive and reliable knowledge base that would form the foundation for rigorous scientific investigations.

The epistemological divide between traditional and allopathic (modern/Western) medicine presents an additional challenge in the evidence-based validation of traditional medicines. This problem is particularly exacerbated by Ethiopia's lack of a comprehensive and reliable database of traditional medicine knowledge. The divergence between the holistic approach of traditional medicine to health and modern medicine's linear and reductionist view complicates the design of clinical trials and the translation of traditional medicine practices into modern medical frameworks (8). As such, there is a need for research that combines ethnomedicine with clinical research, such as observational, randomized controlled trials, and single-case design studies that are designed and carried out in collaboration with TMPs (6, 8). Such interdisciplinary research would enable a more comprehensive understanding of traditional medicine and the conversion between traditional and modern medicine systems. This will also aid in the design of high-quality clinical trials for evaluating traditional use claims.

Fragmented research efforts

One of the defining characteristics of the current traditional medicine research landscape in Ethiopia is the fragmentation of research efforts. The various research and associated regulatory efforts are often scattered, and there is no clear coordination among universities, research institutions, TMPs, regulatory agencies, and other government bodies. This lack of alignment has led to duplication of efforts and inefficient use of resources (3). Therefore, enhancing cooperation through the creation of research networks or consortia is essential to hastening the scientific validation of traditional medicine. The creation of collaborative frameworks helps streamline and sustain efforts, align research agendas, and ensure the effective utilization of resources, ultimately enhancing the im-

port of research efforts. An example of such collaboration is the NEXUS (Network of Excellence for Utilizing Indigenous Medicinal Knowledge Systems) initiative, which aimed at forming a network to introduce effective methodologies for collating Indigenous medicinal knowledge, extend partnerships, strengthen/build capabilities for developing medicinal products from potential medicinal plants, advocate for biodiversity conservation and protection of Indigenous knowledge systems (9).

Regulatory gaps in traditional medicine research

A well-developed regulatory system is an essential factor in realizing the potential of traditional medicine. Despite the advances made, Ethiopia's regulatory landscape does not provide a clear system for the validation of traditional medicines. A notable example in this context is the lack of clinical trial guidelines for traditional medicine. Although drafted, the guidelines have yet to be ratified (3, 10). Moreover, there is a lack of a clear and consistent regulatory definition of what constitutes traditional medicine. There is a wide array of terms used in proclamations, policies, directives, and guidelines that could be interpreted in different ways, such as "traditional drugs", "traditional medicine products", "traditional medicine and alternative and complementary medicine", "traditional medication", and "herbal medicines". Existing regulatory documents are narrowly focused on medicines or products, particularly herbal medicines, while other types of traditional medicine, mainly procedure-based traditional medicine practices, are unaddressed. Generally, there is a lack of conceptualizing traditional medicine as a system of medicine with all its domains similar to its modern counterpart. Given the holistic nature of traditional medicine practices, regulatory guidelines must capture the complexities of traditional medicine, enabling the study of this field not only within the theoretical frameworks of modern medicine but also within its own theoretical frameworks.

Addressing challenges to evidence-based validation

We have proposed three major approaches to increasing the potential and evidence-based utilization of traditional medicines: developing a high-quality national database of traditional knowledge, strengthening collaboration among stakeholders, and enabling regulatory systems (Box 1)

1. Develop a high-quality national Indigenous knowledge repository and evidence-base

- Launch a national community-based recording or documentation initiative.
- Promote high-quality interdisciplinary ethnographic studies, and studies that integrate ethnomedicine with clinical research, and clinical trials.
- Standardize and curate generated knowledge and evidence into a publicly accessible national database.
- Allocate sustained funding for long-term research and capacity building, while encouraging public-private partnerships to leverage additional resources.

2. Strengthen collaboration and coordination among stakeholders

- Establish a dedicated body that will serve as a national hub for research and collaboration.
- Establish multi-stakeholder research consortiums and regular engagement forums.
- Foster interdisciplinary collaboration between TMPs, health professionals, and researchers.

3. Develop an enabling regulatory system

- Enhance the capacity of the regulatory authority with trained personnel and infrastructure.
- Strengthen the clinical trials ecosystem and quality control mechanisms.
- Formulate clear and inclusive guidelines, including clinical trial guidelines, that account for the unique complexities of traditional medicine.

Box 1: Recommendations for addressing the challenges of evidence-based validation of traditional medicine.

Conclusion

Ethiopia faces numerous challenges in the evidence-based validation of traditional medicine, including inadequate documentation of traditional medicine

knowledge, fragmented research efforts, and regulatory gaps. Without addressing these challenges, the opportunities presented by centuries of indigenous knowledge and unique biodiversity will be lost.

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