A Meta-Research Framework for Transparent, Ethically Accountable Integration of CAM

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Conflict of Interest Statement

The author is a licensed acupuncturist and the owner of a private acupuncture and moxibustion clinic in Tokyo. The author previously sold dietary supplements on a small scale, but is no longer engaged in any supplement sales. These professional activities are disclosed for transparency.

The author declares that no financial, commercial, or personal relationships have influenced the content, analysis, or conclusions of this Commentary.

Funding Statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author Contribution

Kenjiro Shiraishi is the sole author of this Commentary and is responsible for all aspects of its content.

Abstract

This paper contributes to meta-research on how clinical claims should be made transparent, reproducible, and auditable under open-science practices. We present a transferable Evidence–Values–Accountability (EVA) framework and use complementary and alternative medicine (CAM) as a testbed to analyze how research evidence, patient values, and institutional accountability can be structurally linked without endorsing specific therapies. The framework operationalizes transparency through repository-ready artifacts—checklists, prompt-preservation templates, preregistration pathways, and workflow logs—that document reasoning, evidence weighting, consent/risk communication, and human oversight. We map EVA to reporting and oversight elements (e.g., data availability, AI-use disclosure, and referral criteria) to reduce ambiguity at the research–practice interface and to improve meta-evaluation of clinical narratives. CAM is analytically useful because

heterogeneity, cultural framing, and evidence gaps make reproducibility and governance challenges salient; recent AI-amplified misinformation (e.g., a bromism case) further illustrates why provenance and disclosure matter. Although demonstrated on CAM, the framework is domain-agnostic and intended for broader health research. By foregrounding research transparency and accountability rather than therapeutic claims, this work advances meta-research on how clinical knowledge is generated, communicated, and audited within open science, and offers concrete tools that health systems and journals can adopt.

Keywords

meta-research; research transparency; reproducibility; open science; auditability; research ethics; reporting standards; AI-use disclosure; CAM; patient values; accountability

1,Introduction (enhanced with AI-related adverse event)

This work is positioned as **meta-research**: our primary aim is to design and evaluate transparent, reproducible, and auditable processes for making and communicating clinical claims under open-science practices, rather than to argue for or against any specific CAM intervention.

Complementary and alternative medicine (CAM), including acupuncture, is used by millions worldwide, yet remains insufficiently integrated into healthcare systems. This gap is becoming increasingly urgent, not only because CAM has long been part of the global health landscape, but because the accelerating adoption of artificial intelligence (AI) in clinical decision-making will inevitably intersect with CAM—making it essential to establish a robust integration framework before unsafe practices take root.

First, declining trust in healthcare institutions and the spread of health misinformation—exemplified by the global rise in vaccine hesitancy—have increased the appeal of CAM【1,2】. Such distrust can drive patients toward interventions that lack robust evidence and may delay or replace effective treatment.

Second, rising healthcare costs are placing greater financial burdens on individuals, prompting some to seek care options perceived as more affordable or accessible, including CAM【3】. In Canada, for example, high out-of-pocket costs for prescription drugs have been shown to create inequities in access and lead patients to delay or forgo necessary conventional care【4】. Such financial barriers can make lower-cost or perceived-accessible options, including CAM, more attractive, even when those options lack strong evidence.

Third, the rapid clinical adoption of AI in diagnosis and treatment recommendations makes CAM integration an urgent policy and safety issue. AI will inevitably enter the CAM space, but without a clear decision-making framework, it risks amplifying existing biases and promoting unsafe practices.

A recent case report illustrates this danger: a patient developed bromism after following ChatGPT's advice to substitute sodium chloride with sodium bromide, obtained online【5】. The AI-generated suggestion lacked contextual risk assessment or appropriate health warnings. This led to months of bromide ingestion, resulting in neuropsychiatric symptoms, electrolyte disturbances, and hospitalization. The case underscores how AI can provide decontextualized, inaccurate health information, potentially leading to preventable harm—particularly when patients are seeking "natural" or alternative solutions.

Although the cultural expressions and regulatory environments surrounding CAM vary—from Europe's formalized herbal pharmacopoeias to rapidly expanding CAM markets in the Global South—the underlying challenges of ensuring safety, evidence-based practice, and ethical integration are strikingly consistent across regions.

These converging factors make it imperative to redefine how CAM is structured within modern healthcare. We propose a tripartite model balancing evidence-based shared decision making (SDM), respect for patient values, and ethical accountability. This model provides a safeguard for responsible CAM integration and a necessary foundation for safe, trustworthy AI-assisted decision support.

2,Current challenges in CAM integration

Complementary and alternative medicine (CAM) encompasses a wide range of culturally rooted practices. The World Health Organization (WHO) defines CAM as “approaches that often complement or substitute for mainstream medicine”【6】, while the U.S. National Center for Complementary and Integrative Health (NCCIH) distinguishes between “complementary” methods—used alongside conventional treatments—and “alternative” methods, which are used in place of them【7】.

Table 1 summarizes common categories and examples of CAM modalities relevant to this discussion.

Categories and Examples of Complementary and Alternative Medicine (CAM)

Category	Examples
Traditional East Asian medicine	Acupuncture, moxibustion, Kampo (Japanese herbal medicine)
Mind-body practices	Yoga, meditation
Natural products	Herbal supplements, dietary botanicals
Manual therapies	Chiropractic, massage

Table 1 outlines common examples of CAM modalities relevant to this discussion.

Despite their diversity and popularity, CAM modalities face persistent challenges that hinder their ethical and effective integration into healthcare systems:

2-1.Lack of standardized protocols

Acupuncture techniques and herbal formulations vary widely, with limited regulation of quality, dosage, or preparation【8】. This variability undermines reproducibility and complicates the generation of high-quality evidence【9】.

2-2.Dependence on contextual and placebo-related effects

Treatment outcomes in CAM are strongly influenced by cultural narratives, therapeutic rituals, and the patient–practitioner relationship. Furthermore, research in medical communication has shown that the way information is

conveyed and the process by which patients participate in decision-making can themselves affect therapeutic outcomes through placebo effects【10】. Such insights are applicable to the design and practice of shared decision making (SDM) in CAM, offering important guidance for balancing cultural elements with evidence-based approaches.

2-3.Over-reliance on patient preference without adequate safeguards

Patient values are central to person-centered care, but uncritical deference can lead to ethically and clinically problematic situations, such as substituting CAM for proven treatments, delaying diagnosis, or promoting costly but ineffective therapies【11】.

In conditions that remain difficult to manage with conventional medicine—such as chronic dizziness, persistent night sweats, or medically unexplained fatigue—patients often turn to CAM【6,7,12,13】. Without a structured decision-making model, these choices can be inconsistent, ethically ambiguous, and potentially unsafe.

3,The tripartite model

We propose a tripartite model for the ethical integration of CAM into modern healthcare, comprising three interdependent pillars:

3-1.Evidence-based shared decision making (SDM)

Shared decision making (SDM) is a collaborative process in which clinicians and patients exchange the best available evidence to arrive at treatment choices that align with the patient's values and preferences【14】. In the context of CAM, it is essential to present biomedical evidence pertaining to conventional standard-of-care interventions alongside CAM-specific evidence, including a transparent discussion of their respective limitations. This balanced presentation ensures that patients can make informed decisions within a clear evidentiary framework. The foundation of this process rests on evidence-based medicine (EBM)**,** which demands that clinical decisions be grounded in transparent, reproducible, and reliable data.

3-2.Respect for patient values

Patients bring unique cultural perspectives, life experiences, and treatment goals to clinical encounters. These values can strongly influence their openness to CAM. In East Asian contexts, concepts such as *Qi* stagnation or blood deficiency may serve as explanatory models that foster patient engagement【15】. However, such concepts should be framed as interpretive tools rather than biomedical diagnoses, and they must not replace biomedical assessment.

3-3.Ethical accountability

Clinicians have a responsibility to communicate uncertainties, avoid deception, and ensure that patients are not misled by overpromising outcomes. This is especially important in CAM, where reproducibility of results can be limited and patient expectations are often shaped by anecdote or cultural narratives【10】. Ethical accountability also encompasses recognizing the limits of one's professional scope and, when appropriate, referring patients to conventional medical care. This obligation is supported by ethical and legal frameworks that require CAM practitioners to make such referrals when a patient's condition falls outside their area of competence【16】.

Neglecting any one of these pillars undermines the quality, safety, and social value of CAM integration. For example, focusing solely on patient preference without sufficient evidence risks promoting interventions that are ineffective or harmful; conversely, focusing exclusively on evidence without cultural sensitivity may erode trust and reduce adherence【17，18】.

Figure 1. The Tripartite Model for CAM Integration.

A balanced integration of three essential elements—evidence-based shared decision making (SDM), respect for patient values, and ethical accountability—is necessary

for the responsible incorporation of complementary and alternative medicine into modern healthcare systems.

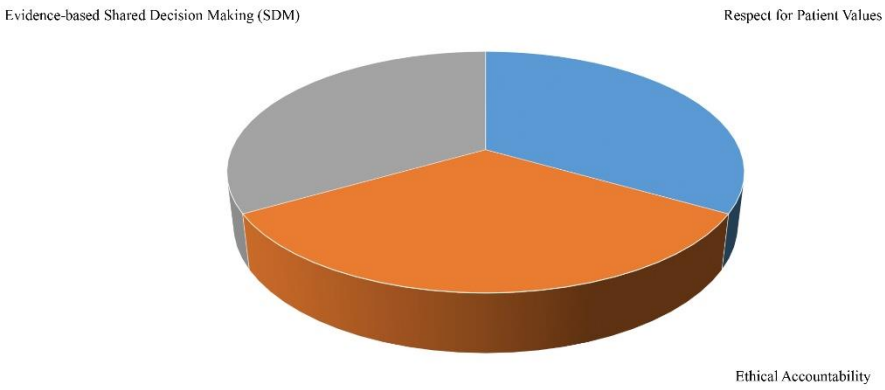

Figure 1. Tripartite Model for CAM Integration: Balanced integration of these values is essential for ethical and effective practice.

4. Operationalizing Transparency: Repositories, Checklists, Prompt Logs, and Preregistration

Operationalization**.** We operationalize the EVA framework with repository-ready artifacts: (a) an EVA Checklist (v1.0) that externalizes evidence weighing, value trade-offs, and accountability points; (b) a Prompt-Preservation Log Template to capture AI-mediated authoring and decision support; (c) an OSF preregistration pathway for protocol-level commitments; and (d) a Workflow Log Schema for provenance and audit trails. To avoid therapeutic inference, we use a synthetic test case solely to demonstrate documentation—no clinical outcomes are reported. The

case shows how referral criteria, uncertainty statements, consent/risk communication, and AI-use disclosure are recorded to enable transparency and auditability across contexts.

Synthetic test case (documentation only). An adult patient presents with persistent dizziness of unclear origin. Before any CAM consideration, the EVA Checklist records biomedical exclusion steps (e.g., acute cerebrovascular or inner-ear emergencies ruled out; red-flags documented), ongoing standard care (primary physician follow-up confirmed), and referral criteria should warning signs emerge. CAM is framed as adjunctive; the consent note explicitly states uncertainty of benefit, variability of response, and that CAM does not replace diagnostics or effective treatment. The Prompt-Preservation Log records any AI-assisted authoring or counseling, including model/version, input prompts, and generated text retained as an artifact. The Workflow Log links each step (screening → consent language → referral thresholds → AI-use disclosure) with timestamps and repository identifiers, enabling independent meta-evaluation of claim-making and governance.

To enhance transparency, a patient-facing reflection worksheet was provided to clarify the patient's understanding, expectations, and concerns. This approach aligns

with best-practice shared decision making【14】and with CONSORT 2025 guidance to document care processes in addition to reporting outcomes【19】.

Based on the EVA schema and its documentation artifacts, we outline a four-step framework for ethically integrating CAM into modern medicine (Table 2).

Table 2. Four-step framework for ethical integration of CAM into modern medicine

Four-Step Framework for Ethically Integrating CAM

Step	Description
1. Present biomedical and CAM evidence (including limitations); elicit patient preferences	Prioritize presenting biomedical evidence before discussing CAM, ensuring patients understand standard treatments before considering complementary approaches.
2. Formulate a shared care plan	Collaborate with other physicians or family members as needed, using biomedical terminology rather than culture-specific concepts to maintain clear, shared understanding.
3. Use reflective worksheets to assess patient understanding, concerns, and hopes	Provide patients an opportunity to organize and express their thoughts, worries, and expectations in their own words, which can then be shared with the care team.
4. Incorporate patient feedback and adjust the plan as needed	Remain flexible and update the care plan in response to changing circumstances or patient input, ensuring care stays aligned with patient needs.

Table 2. A structured process for ethically integrating CAM into patient care

This framework serves dual purposes:

- Clinical safety**:** Ensures CAM use complements, rather than replaces, effective biomedical care.
- Ethical transparency**:** Creates a clear, auditable record of the decision-making process.

Looking ahead, embedding this framework into AI-assisted decision-support tools could help mitigate bias, ensure cultural sensitivity, and maintain patient trust. By explicitly integrating evidence, values, and ethical safeguards, AI could support—not undermine—responsible CAM use.

These artifacts are domain-agnostic; CAM serves only as a testbed to surface reproducibility and governance challenges that the framework addresses.

5.Conclusion

The ethical integration of complementary and alternative medicine (CAM) into modern healthcare demands more than respect for patient preferences. Without robust structural safeguards, CAM use risks inconsistency, ethical ambiguity, and patient harm—risks that will only grow as artificial intelligence (AI) enters the clinical decision-making space.

Our tripartite model—balancing evidence-based shared decision making (SDM), respect for patient values, and ethical accountability—offers a practical foundation to address these challenges. Applied through a four-step framework, it promotes safety, transparency, and trust while ensuring CAM complements, rather than replaces, effective biomedical care.

Beyond improving care quality, this approach can help rebuild public trust, align CAM

practices with health system priorities, and create a safer environment for AI-assisted recommendations.

Key messages

- Ethical CAM integration requires evidence-based SDM, respect for patient values, and ethical accountability in equal measure.
- Communicate limitations and uncertainties as clearly as benefits.
- A four-step framework can translate these principles into daily clinical practice.
- Embedding this model in AI-driven recommendations is essential to protect patients and maintain trust.

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