

# INPLASY

## Navigating uncertainty in evidence-informed decision-making for traditional, complementary, and integrative medicine: an updated critical interpretive review

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### ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Piloting of the study selection process.

**Conflicts of interest** - The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

**INPLASY registration number:** INPLASY202510066

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 January 2025 and was last updated on 18 January 2025.

### INTRODUCTION

**Study aim** This review aims to provide actionable insights to inform evidence-informed decision-making for guidelines and policies on traditional, complementary and integrative medicine (TCIM), so as to enhance the transparency, trustworthiness, and contextual relevance of these decisions and recommendations, particularly in the context of evidence uncertainty and/or paucity.

The review's compass question is: How can nationally and internationally endorsed guideline development consensus statements, alongside other strategies and frameworks, be applied when making evidence-informed decisions for guidelines and policies on TCIM, especially when there is insufficient or uncertain empirical evidence about benefits or harms?

**Background** The demand for evidence-informed recommendations for traditional, complementary, and integrative medicine (TCIM) is growing among patients, practitioners, and policymakers. TCIM encompasses a diverse set of systems, practices and products that are not typically part of conventional Western biomedicine. The widespread use of TCIM, coupled with their potential to help reduce the global burden of disease and promote wellness, makes them a critical, yet complex component of healthcare systems. Moreover, TCIM has been identified as an important contributor to achieving the United Nations' Sustainable Development Goals (SDGs) and universal health coverage (UHC), underscoring the urgent need for robust and contextually relevant TCIM guidelines [1].

Despite this, systematic reviews of clinical practice guidelines (CPGs) frequently report that TCIM is

either overlooked or underrepresented, with many guidelines deemed low quality and lacking transparency. Many TCIM-specific CPGs are also of low quality. Additionally, due to insufficient empirical evidence, it is common for recommendations to only be informed by expert opinion and/or traditional knowledge.

To support systematic, transparent decision-making in health care, numerous consensus statements exist. International examples include the 'WHO Handbook for Guideline Development' [2] and 'Grading Recommendations Assessment Development Evaluation' (GRADE) [3]. Designed predominantly for biomedical contexts, their application to TCIM can be challenging due to the many diverse practices, different therapeutic paradigms, and complex cultural, historical and sociopolitical contexts. Moreover, empirical evidence on TCIM's benefits or risks is often lacking or of low quality, making evidence-informed decisions more difficult.

In response to these challenges, a 2017 critical interpretive review by Hunter et al. [4] identified and appraised the relevance of eight internationally or nationally endorsed guideline development consensus statements published between 1995 and 2015. Five main themes emerged: the importance of framing the question; limitations of an evidence hierarchy; strategies for dealing with insufficient evidence; qualifying a recommendation; and structured consensus development. When making recommendations, along with evidence about benefits and risks, modifying factors such as stakeholder values, demand, costs, equity and feasibility must also be considered.

Since the 2017 review, there have been substantial methodological advancements in evidence-informed decision-making for guideline developers. Both GRADE and the WHO have provided more explicit guidance for their evidence-to-decision (EtD) frameworks [5, 6] and the use of qualitative research in decision-making [7, 8]. Notably, the WHO launched WHO-INTEGRATE in 2019 [6]. The WHO-EtD framework is designed to handle complex health issues and aims to foster a whole-of-society-perspective by also addressing factors beyond clinical effectiveness, benefits and harms. These include human rights and sociocultural acceptability; health equity, equality, and non-discrimination; societal implications; financial and economic considerations; and feasibility and health system considerations. Leading on from this, the 'WHO guide for evidence-informed decision-making' published in 2021 [9], along with a repository of vetted tools,

provides a multidisciplinary framework for incorporating diverse forms of evidence to inform clinical, public health and health system decision-making and policy.

Other work relevant to TCIM includes two TCIM extensions to the 'Reporting Items for practice Guidelines in Healthcare' (RIGHT) – one for acupuncture [10] and the other for traditional Chinese medicine [11] – have also been developed with the aim of improving the quality of TCIM guidelines and suitability of the RIGHT appraisal tool. The TCIM guidelines developers highlight several challenges with using the RIGHT Statement due to its biomedical focus. Modifications to the reporting items address the importance of also describing the condition, epidemiology, pathogenesis, diagnosis, treatment rationale, intervention etc. from the TCIM perspective. TCIM scholars have also written extensively on how to apply existing guideline development consensus statements such as GRADE [12], and potential modifications or alternatives aimed at improving their applicability for TCIM contexts [13-15].

**Rationale** The primary aim of this review is to evaluate national and international guideline development consensus statements, as well as other strategies and frameworks for evidence-informed decision-making in guidelines and policies and interpret their applicability to TCIM. The review responds to the growing demand for high-quality, evidence-informed TCIM recommendations that are both trustworthy and contextually appropriate.

While the 2017 review by Hunter et al. [4] provides valuable insights for addressing the challenges of TCIM guideline development, the field has substantially evolved. An updated review is needed to incorporate more recent advancements in methodology and practice. Additionally, this review will expand the scope of the original review to also consider informal strategies so as to ensure perspectives relevant to TCIM are adequately captured.

A particular focus of this review is strategies for managing evidence uncertainty, a persistent challenge in TCIM guideline development due to the limited availability of high-quality empirical data. This review will identify existing methods for addressing insufficient or inconsistent evidence. For instance, EtD frameworks, such as GRADE and WHO-INTEGRATE, provide structured approaches to incorporating diverse evidence sources and modifying factors into the decision-

making processes. Modifying factors relevant to TCIM include stakeholders' values and preferences, health equity, sociocultural acceptability, and feasibility, to name a few. These factors may lead to stronger recommendations being made despite low certainty evidence, and vice versa.

The systematic application of EtD frameworks has the potential to reconcile rigid biomedical evidence hierarchies with other paradigms and worldviews relevant to TCIM. However, despite these advancements, such frameworks were originally developed within a biomedical context. Critical questions remain. For example, how might these frameworks rigorously and transparently accommodate Traditional Knowledge, which is deeply respected by TCIM practitioners and trusted and valued by many consumers and patients?

By bridging the gap between biomedical strategies and the unique needs of TCIM, this review seeks to offer actionable insights for guideline developers and policymakers. In doing so, it will contribute to the advancement of evidence-informed decision-making in TCIM, ensuring that future guidelines and policies better support patients, practitioners, health systems and communities worldwide.

## METHODS

**Search Strategy** The search strategy is designed to update the 2017 critical interpretive review of consensus statements on guideline development [4]. Unlike systematic reviews, literature searches for critical interpretive reviews/syntheses do not need to be comprehensive to answer the review question [16]. Non-systematic methods such as citation and project tracking, snowballing methods, and targeted, purposive searches are commonly used to complement systematic database searches. Therefore, the following rapid review (RR) methods will be employed. Only three databases will be searched using limited, focused search terms aimed at optimising specificity over sensitivity, and website searches for grey literature will focus on the previously included guideline development consensus statements. Single reviewers will undertake the screening of database search results, followed by a second reviewer who will screen the excluded publications and reincluded any they considered relevant. The list of included publications will be finalized through consensus and involving additional reviewers if required.

PubMed, CINAHL via EBSCOHost, and AIMED via OVID will be searched from inception to identify articles published in any language that described EtD frameworks used in any health care setting and for articles that recommend strategies for TCIM guidelines or policies.

PubMed search terms: ("evidence to decision"[Title/Abstract]) OR (("clinical guideline\*" [Title/Abstract] OR "clinical practice guideline\*" [Title/Abstract]) AND ("medicine, traditional"[MeSH Terms] OR "complementary therapies"[MeSH Terms] OR "integrative medicine"[MeSH Terms])).

CINHAL search terms: (TI ("evidence to decision") OR AB ("evidence to decision")) OR ((TI ("clinical guideline\*") OR AB ("clinical guideline\*") OR TI ("clinical practice guideline\*") OR AB ("clinical practice guideline\*")) AND ((MH "Medicine, Traditional+") OR (MH "Integrative Medicine+") OR (DE "TRADITIONAL medicine") OR (DE "INTEGRATIVE medicine") OR TI Traditional N5 (medicine OR medicines) OR AB Traditional N5 (medicine OR medicines))

AIMED search terms: ("evidence to decision" or "clinical guideline\*" or "clinical practice guideline\*").ab.ti. AND ((exp traditional medicine/ or exp Medicine, Traditional/ or exp Complementary Therapies/ or exp Integrative Medicine/) or (Traditional adj5 medicin\*).ab.ti.)

The websites of the previously included guideline development consensus statements will be manually searched for updates and any new statements. Searches will be augmented through citation and project tracking and bibliographic cluster searching, along with relevant publications known to reviewers. If additional targeted database searches are conducted post hoc, these will be transparently reported.

**Eligibility criteria** Any nationally or internationally endorsed guideline development consensus statement (published in a peer review journal or grey literature) that provides formal guidance for decision-making in health care settings is included. For those with multiple iterations, only the most recent edition of a statement is included. Publications in peer reviewed journals are only included if the article is an addendum to the consensus statement. Commentaries on, explanatory articles, and studies evaluating guidelines and consensus statements are excluded.

Any TCIM-specific guidance for clinical practice guideline development or evidence-informed policy-making published in a peer review journal is included, irrespective of whether it is endorsed by an organization or government body. TCIM-specific guidelines or their protocols are only included if they provide TCIM-specific recommendations for guideline development or policy decision-making. Other guidelines, even if they consider TCIM are excluded. Conference abstracts are excluded.

There are no restrictions on publication date or language.

**Data extraction** Basic data extraction about the publications will include the publication year, the type of publication, topic and its relevance to key themes and subthemes, and whether it pertains to biomedicine, TCIM or both. Single reviewers will extract this data into a pre-piloted data extraction form. A second reviewer will verify the accuracy. Any disagreements will be resolved through consensus and involve other reviewers if required.

#### **Strategy of data synthesis / Statistical analysis**

The interpretive analysis methods described in the original 2017 review will be applied [4, 16]. Following basic data extraction, included publications will be purposively selected for more in-depth analysis based on their relevance to the review question, with criteria focused on methodological rigor and contribution to thematic exploration and development. This approach aims to ensure a systematic, yet flexible analysis, yielding insights into strategies for guideline development and evidence-informed decision-making that is able to address the complexities of TCIM.

Thematic analysis will begin deductively according to the original review themes. As new findings and themes emerge, these will be iteratively interrogated and developed with the aim of interpreting how the updated findings may be applied to TCIM guideline development. The iterative process will involve revisiting data and themes, allowing for a dynamic interaction between emerging insights and interpretive analysis.

As per the original review [4], strategies for guideline development and decision-making will be compared for similarities (reciprocal translational analysis) and contradictions (refutational synthesis). Lines-of-arguments (synthesising arguments) will be generated by integrating the content and themes identified from the included

publications to identify overarching themes and constructs, and interpret how they apply to TCIM. Reflexivity will be maintained throughout, with explicit acknowledgment of the reviewers' perspectives and potential biases in interpreting the data.

**Country(ies) involved** Australia, China.

**Keywords** Traditional medicine, Complementary therapies, Integrative medicine, Clinical Practice Guidelines, Evidence to Decision Framework, Decision Making, Guideline Development.

**Dissemination plans** The review will be submitted for publication in a peer review journal. The authors may promote and distribute the findings through their networks.

#### **Contributions of each author**

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