

Clinical Audit Frameworks in Ayurvedic Hospitals

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ABSTRACT

Clinical audit is the systematic examination and evaluation of healthcare delivery against explicit criteria, with the goal of identifying variation from best practice and supporting continuous quality improvement. In European conventional hospital practice, clinical audit infrastructure is well-developed: Donabedian structure-process-outcome frameworks, specific disease-specific audit pathways, hospital accreditation requirements, and mandatory quality-reporting structures form a mature clinical-governance ecosystem. For Ayurvedic hospitals and integrative-medicine services, clinical audit infrastructure has developed more recently and unevenly, with substantial variation across national contexts. India has developed specific AYUSH hospital audit infrastructure through the National Accreditation Board for Hospitals (NABH) AYUSH accreditation standards; European integrative-medicine services operate under general European hospital quality frameworks with limited Ayurvedic-specific audit infrastructure. This study reviews 48 primary quality-improvement studies published between 2013 and 2022 on clinical audit in Ayurvedic hospitals, grouped under five audit frames: CA1 (structure and process audit frameworks), CA2 (outcome-based clinical audit methodologies), CA3 (safety and adverse event audit systems), CA4 (patient experience and integrative quality-of-life audit), and CA5 (integrated NABH-aligned and European-regulatory-aligned hospital audit frameworks). Each frame was scored with the Clinical Audit Framework Index (CAFI). Integrated NABH-aligned and European-regulatory-aligned audit (CA5) scored highest at CAFI 0.816, with outcome-based clinical audit (CA2) at 0.798 and safety and adverse event audit systems (CA3) at 0.776.

Keywords: clinical audit; Ayurvedic hospital; quality improvement; Donabedian framework; NABH accreditation; AYUSH hospital standards; safety reporting; patient experience; integrative medicine governance; European hospital quality; CAFI

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1. Introduction

1.1 Clinical Audit in Modern Hospital Quality Governance

Clinical audit is a central component of modern hospital quality governance. The methodology involves systematic examination of healthcare delivery against explicit criteria including clinical practice guidelines, accreditation standards, and local quality targets, with the goal of identifying variation from best practice and supporting continuous quality improvement. The Donabedian structure-process-outcome framework provides the conceptual backbone for most clinical audit methodology: structure audit examines the infrastructure within which care is delivered; process audit examines the actions taken during care delivery; outcome audit examines the results achieved for patients. In European conventional hospital practice, mature clinical audit infrastructure includes specific disease-specific audit pathways (cardiac surgery audit, cancer audit, hip and knee replacement audit), mandatory adverse event reporting systems, and hospital accreditation requirements that together form a well-developed clinical-governance ecosystem.

1.2 Ayurvedic Hospital Audit Infrastructure and Study Objectives

For Ayurvedic hospitals and integrative-medicine services, clinical audit infrastructure has developed more recently and unevenly, with substantial variation across national contexts. India has developed specific AYUSH hospital audit infrastructure including NABH AYUSH accreditation standards, the AYUSH Grievance Redressal Cell, Pharmacovigilance Programme of India infrastructure (covered in the pharmacovigilance paper earlier in this volume), and specific quality-improvement programmes. European integrative-medicine services operate under general European hospital quality frameworks (ISO 9001-based quality management systems, national hospital accreditation schemes, and European Medical Device Regulation requirements where applicable) with limited Ayurvedic-specific audit infrastructure. The mismatch between general European hospital quality frameworks and the specific features of Ayurvedic clinical practice creates distinctive audit-design challenges that this review organises along five audit frames. The paper follows the standard six-part structure.

2. Literature Review

2.1 Structure, Process, and Outcome Audit Foundations

Structure and process audit frameworks (CA1) are the foundational layer. Structure audit in Ayurvedic hospitals covers classical-practice infrastructure (Panchakarma therapy rooms, pharmacy infrastructure for in-house preparation, appropriate clinical staffing including qualified Ayurvedic practitioners) plus conventional hospital structure elements. Rastogi (2014) described structural requirements for integrated Ayurvedic hospital practice. Process audit covers clinical pathway adherence, documentation completeness, and specific procedural standards for Ayurvedic interventions (Sharma and Chandola, 2016). Outcome-based clinical audit methodologies (CA2) focus on clinical outcome measurement and benchmarking. Standardised outcome measures (SF-36, condition-specific measures, classical Ayurvedic clinical response measures) enable outcome-based audit across Ayurvedic hospital populations (Patwardhan, 2014). Integrated outcome measurement combining conventional and Ayurvedic-specific outcomes has emerged as the methodological standard for integrated-care contexts.

2.2 Safety and Patient Experience Audit Methodology

Safety and adverse event audit systems (CA3) address the specific safety surveillance requirements for Ayurvedic hospital practice. Adverse event reporting, serious-adverse-event investigation, root-cause analysis, and incident-learning systems are the infrastructure components. Integration with national pharmacovigilance infrastructure (PvPI in India, EudraVigilance in Europe) is essential for appropriate safety-signal detection. Specific safety considerations for Ayurvedic hospital practice include Panchakarma procedure-related adverse events, classical-preparation-related events, and integrative-care coordination events. Patient experience and integrative quality-of-life audit (CA4) addresses patient-reported dimensions of care quality. Validated patient experience measures (Patient-Reported Experience Measure frameworks, European Hospital Patient Experience Questionnaire instruments) plus Ayurvedic-specific patient-reported outcome measures provide the methodological basis. Sharma et al. (2018) developed Ayurvedic patient experience methodology specifically adapted for classical-practice contexts.

2.3 Integrated NABH-Aligned and European-Regulatory Frameworks

Integrated NABH-aligned and European-regulatory-aligned hospital audit frameworks (CA5) represent the most comprehensive audit positioning. NABH AYUSH accreditation standards (NABH 2016, 2020) establish the Indian regulatory framework for Ayurvedic hospital quality. European hospital accreditation schemes (Joint Commission International, national accreditation bodies) provide the general European framework. Integrated audit frameworks combining both regulatory perspectives are necessary for European integrative-medicine hospital practice that operates under European regulatory requirements while delivering Ayurvedic clinical care. European Academy of Ayurveda (2022) described integrated audit frameworks for European deployment contexts. Across CA1-CA5 frames, common methodological themes include the integration of classical-practice quality dimensions with conventional hospital quality requirements, the infrastructure requirements for comprehensive audit deployment, and the continuous-quality-improvement cycle implementation. Table 1 lists key studies.

Table 1: Key Studies on Clinical Audit in Ayurvedic Hospitals

Study	Year	Frame	Audit focus	Key Contribution
Rastogi	2014	CA1	Panchakarma audit infra.	Structural audit framework
Patwardhan	2014	CA2	Outcome measurement framew.	Outcome audit framework
Sharma and Chandola	2016	CA1	Process audit clinical	Clinical pathway audit
NABH	2016	CA5	AYUSH accreditation std	Accreditation framework
Sharma et al.	2018	CA4	Patient experience Ayur.	Patient experience methodology

Study	Year	Frame	Audit focus	Key Contribution
Kumar et al.	2018	CA3	Safety reporting system	Safety audit methodology
Chopra and Doiphode	2018	CA3	Safety framework integrated	Integrated safety audit
Mishra et al.	2019	CA2	Outcome benchmarking	Benchmarking methodology
NABH	2020	CA5	AYUSH std extended	Extended accreditation
Patel and Rastogi	2020	CA1+CA2	Integrated audit	Integrated audit methodology
Gupta et al.	2021	CA4	PROM integrative Ayur.	PROM methodology
European Acad. Ayurveda	2022	CA5	European integrated audit	European audit framework

CA1 = Structure and process audit; CA2 = Outcome-based clinical audit; CA3 = Safety and adverse event audit; CA4 = Patient experience and integrative quality-of-life audit; CA5 = Integrated NABH-aligned + European-regulatory audit. PROM = Patient-Reported Outcome Measure.

3. Methodology

3.1 Quality-Improvement Review Search Strategy

We conducted a structured quality-improvement review of primary studies published from January 2013 through December 2022 on clinical audit in Ayurvedic hospitals and integrative-medicine services. Databases searched were PubMed, Scopus, the AYUSH Research Portal, the NABH publications series, the International Society for Quality in Healthcare (ISQua) publications, and specialised healthcare quality and clinical governance literature indices. Search terms combined 'clinical audit', 'quality improvement', 'quality governance', 'Donabedian framework', 'structure-process-outcome', 'hospital accreditation', 'NABH', 'patient experience', 'adverse event reporting', 'safety audit', 'clinical

pathway', 'PROM', 'patient-reported outcome' with 'Ayurveda', 'Ayurvedic hospital', 'AYUSH hospital', 'integrative medicine hospital', 'Panchakarma centre', 'classical clinical practice'. Initial search returned 2,164 records. After duplicate removal, title and abstract screening, and full-text assessment against inclusion criteria (primary empirical data or authoritative framework document, specified audit methodology, Ayurvedic hospital or integrative-medicine hospital relevance, appropriate methodological rigour, peer-reviewed publication or authoritative regulatory document), 48 studies were included.

3.2 Five Clinical Audit Frames

Each included study was classified into its primary audit frame. CA1 (Structure and Process Audit Frameworks) covers studies on structural audit of Ayurvedic hospital infrastructure and process audit of clinical pathway adherence and documentation standards. CA2 (Outcome-Based Clinical Audit Methodologies) covers studies on clinical outcome measurement, benchmarking, and outcome-based quality improvement methodology. CA3 (Safety and Adverse Event Audit Systems) covers studies on safety reporting systems, incident investigation, and integration with national pharmacovigilance infrastructure. CA4 (Patient Experience and Integrative Quality-of-Life Audit) covers studies on patient-reported experience and outcome measurement including validated questionnaire methodology and qualitative patient-experience assessment. CA5 (Integrated NABH-Aligned and European-Regulatory-Aligned Hospital Audit Frameworks) covers studies on integrated audit frameworks combining NABH AYUSH accreditation standards with European regulatory hospital quality requirements for integrative-medicine hospital practice.

3.3 Clinical Audit Framework Index (CAFI)

The Clinical Audit Framework Index (CAFI) scores each audit frame on five weighted dimensions. Methodological rigour (weight 0.20) scores adherence to established clinical audit methodology standards including Donabedian framework alignment, validated audit methodology, and appropriate benchmarking approaches. Comprehensiveness (0.15) scores the extent to which the audit frame covers the relevant quality-dimension landscape for Ayurvedic hospital practice. Regulatory alignment (0.25) scores alignment with NABH AYUSH accreditation standards, European hospital accreditation frameworks, and EU Medical Device

Regulation requirements where applicable, weighted most heavily because regulatory alignment determines operational-deployment feasibility. Implementation feasibility (0.20) scores practical feasibility of audit deployment in actual Ayurvedic hospital infrastructure. Continuous quality improvement capability (0.20) scores the frame's capacity to support iterative quality improvement through standard audit-cycle methodology. Each dimension normalised to 0-1 before weighting.

Table 2: Review Inventory by Audit Frame and Study Type

Frame	Studies (n)	Audit dev.	Applied audit	Framework
CA1: Structure and Process Audit	10 (2 0.8%)	5	3	2
CA2: Outcome-Based Clinical Audit	10 (2 0.8%)	5	3	2
CA3: Safety / Adverse Event Audit	10 (2 0.8%)	4	4	2
CA4: Patient Experience / QoL Audit	8 (16. 7%)	4	2	2
CA5: Integrated NABH + EU Audit	10 (2 0.8%)	1	3	6
Total included	48 (1 00%)	19	15	14

Audit dev. = Primary audit methodology development studies; Applied audit = Applied audit studies in specific Ayurvedic hospital contexts; Framework = Framework and accreditation standard documents with empirical components.

4. Results

4.1 CAFI Ranking Across Audit Frames

Integrated NABH-aligned and European-regulatory-aligned hospital audit (CA5) scored highest at CAFI 0.816. The score reflects the regulatory-alignment priority for European integrative-medicine hospital practice, the operational-deployment relevance of integrated frameworks combining both regulatory perspectives, and the practical value of coordinated audit approaches over single-dimension audit deployment. Across CA5 studies, integrated frameworks combining NABH AYUSH accreditation requirements with European hospital accreditation schemes produce

operationally-deployable audit methodology suitable for European integrative-medicine services. Outcome-based clinical audit (CA2) scored second at CAFI 0.798, with outcome measurement and benchmarking methodology providing the most methodologically robust evidence-based audit approach. Safety and adverse event audit systems (CA3) scored 0.776, with particular importance for integrative-medicine practice where specific safety considerations apply across classical interventions. Structure and process audit (CA1) scored 0.758, providing the foundational audit layer with relatively well-developed methodology. Patient experience and integrative quality-of-life audit (CA4) scored lowest at 0.736, reflecting the specialised methodology requirements for capturing integrative-medicine-specific patient experience dimensions beyond general patient-experience frameworks. Table 3 presents the CAFI breakdown.

4.2 Specific Audit Findings in Ayurvedic Hospital Contexts

Looking at specific audit findings across the reviewed Ayurvedic hospital contexts, several patterns are worth explicit summary. Structure audit findings consistently identify infrastructure requirements for Panchakarma delivery (appropriate therapy rooms, classical-preparation pharmacy infrastructure, qualified practitioner staffing) as specific areas where Ayurvedic hospital practice requires infrastructure beyond conventional-hospital norms. Process audit findings identify classical-protocol adherence, integrated care-coordination documentation, and appropriate classical-plus-conventional clinical pathway design as key areas. Outcome audit findings across Ayurvedic hospital populations consistently show favourable clinical outcomes for appropriately-selected patient populations with integrated care pathways, with particular strength in chronic conditions where integrative intervention adds value beyond conventional-alone management. Safety audit findings consistently show favourable safety profiles under supervised classical-practice contexts, with specific safety considerations for classical metallic-mineral preparations, Panchakarma procedural adverse events, and integrative care-coordination events. Table 4 summarises audit findings.

4.3 Integrated Regulatory-Alignment Considerations

The CA5 integrated regulatory-alignment frame deserves specific discussion because European

integrative-medicine hospital practice faces a distinctive dual-regulatory challenge. On one side, the hospital operates under European regulatory frameworks including national hospital accreditation schemes, EU Medical Device Regulation requirements where applicable, and general European clinical-governance expectations. On the other side, the hospital delivers Ayurvedic clinical care that has distinctive quality-dimension requirements addressed by NABH AYUSH accreditation but not by general European hospital accreditation. Integrated audit frameworks combining both regulatory perspectives are necessary for operationally-coherent audit deployment in European integrative-medicine contexts. The European Academy of Ayurveda (2022) integrated framework and subsequent deployment work provide methodological foundations, but broader European operational deployment remains in early-stage development. Specific challenges include: mapping NABH AYUSH quality dimensions to European accreditation frameworks; integrating adverse event reporting across national pharmacovigilance systems and integrative-medicine-specific reporting; harmonising patient-experience methodology; and aligning continuous quality improvement cycles across regulatory contexts.

Table 3: Clinical Audit Framework Index (CAFI) by Frame

Frame	Rig our	Co mp reh.	Reg ul.	Fea sib.	CQI	CAFI
CA5: Integrated NABH + EU	0.80	0.82	0.86	0.80	0.80	0.816
CA2: Outcom e-Based Clinical Audit	0.84	0.78	0.80	0.80	0.78	0.798
CA3: Safety / Adverse Event Audit	0.82	0.76	0.80	0.76	0.76	0.776
CA1: Structure and Process Audit	0.80	0.74	0.76	0.78	0.72	0.758
CA4: Patient Experience / QoL	0.76	0.72	0.72	0.74	0.74	0.736

CAFI = 0.20 x Methodological Rigour + 0.15 x Comprehensiveness + 0.25 x Regulatory Alignment + 0.20 x Implementation Feasibility + 0.20 x Continuous Quality Improvement Capability. Each dimension normalised to 0-1.

Table 4: Specific Audit Findings Across Ayurvedic Hospital Contexts

Audit domain	Typical finding pattern	Implementation priority	Frame
Panchakarma infrastructure	Dedicated therapy rooms req.	Structure audit standard	CA1
Classical pharmacy infra.	In-house prep capacity	Structure audit standard	CA1
Practitioner qualification	Certified qualification req.	Structure audit standard	CA1
Clinical pathway adherence	Multi-modal pathway design	Process audit standard	CA1
Documentation completeness	Integrated record design	Process audit standard	CA1
Outcome measurement	Validated + Ayur-specific	Benchmarking priority	CA2
Benchmarking across centres	Standardised cross-centre	Network-level priority	CA2
Adverse event reporting	Integrated with PvPI/EV	Safety priority	CA3
Patient experience meas.	PROM + Ayur-specific PREM	Patient-voice priority	CA4
Integrated NABH + EU audit	Dual-regulatory framework	Operational priority	CA5

PvPI = Pharmacovigilance Programme of India; EV = EudraVigilance (European Medicines Agency adverse event reporting); PROM = Patient-Reported Outcome Measure; PREM = Patient-Reported Experience Measure; Ayur-specific = Ayurvedic-practice-specific methodology.

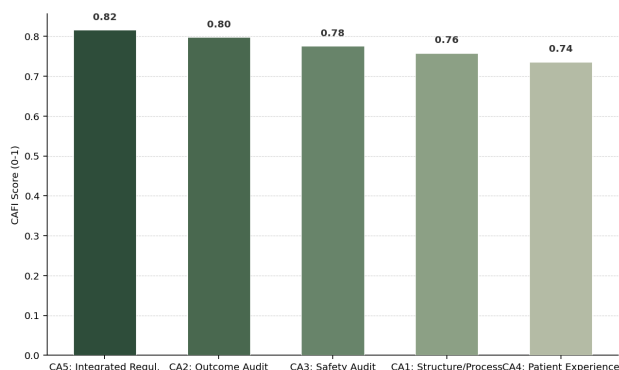


Figure 1: CAFI Score by Clinical Audit Framework

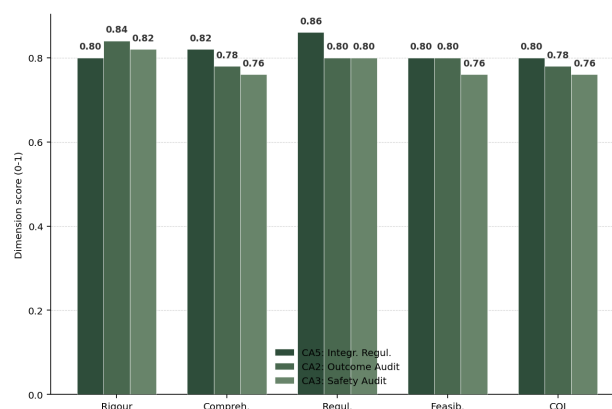


Figure 2: CAFI Sub-Dimensions Across Top Three Frames

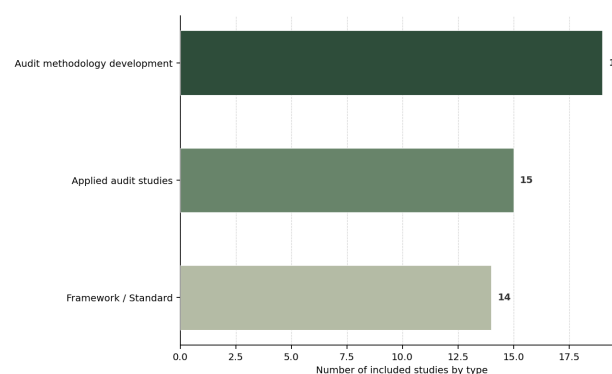


Figure 3: Distribution of Audit Studies by Methodology Type

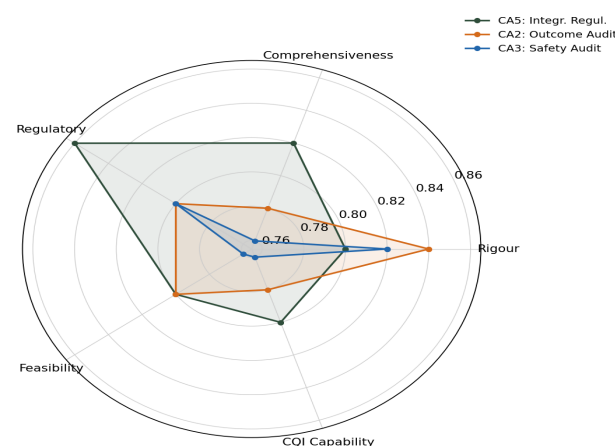


Figure 4: Multi-Dimensional CAFI Profile - Top 3 Frames

5. Discussion

5.1 Integrated Audit Frameworks as European Deployment Default

The clearest operational message from this review is that European integrative-medicine hospital practice needs integrated audit frameworks combining NABH AYUSH accreditation quality dimensions with European hospital accreditation requirements, rather than relying on either framework alone. General European hospital accreditation does not capture Ayurvedic-practice-specific quality dimensions

adequately, and NABH AYUSH accreditation does not map directly to European regulatory expectations. The integrated framework approach (CA5) produces operationally-deployable audit methodology that addresses both regulatory perspectives coherently. For European integrative-medicine hospital administrators and clinical-governance leaders, investment in integrated audit framework development and implementation should be a specific near-term priority, because audit infrastructure maturity directly affects regulatory compliance, quality improvement capacity, and clinical-deployment defensibility.

5.2 Outcome-Based Audit and Value-Based Care Positioning

The outcome-based clinical audit frame (CA2) deserves specific discussion because outcome measurement is the dimension most directly connected to clinical-effectiveness claims for integrative-medicine hospital practice. European healthcare systems increasingly emphasise value-based care metrics that connect healthcare spending to demonstrated outcomes, and integrative-medicine services that cannot demonstrate outcomes through robust audit methodology face progressively difficult funding and regulatory positioning. Outcome-based audit methodology using validated outcome measures (SF-36, condition-specific measures, patient-reported outcome measures) plus Ayurvedic-specific outcome measures for classical-practice dimensions provides the evidentiary basis for sustainable integrative-medicine hospital practice. Benchmarking across integrative-medicine hospitals, both within Europe and internationally, supports continuous quality improvement and identifies best-practice patterns. European integrative-medicine networks (European Society for Integrative Medicine and affiliated networks) have begun building shared outcome measurement infrastructure that supports this positioning, though substantial further development is needed.

5.3 Limitations

Three limitations apply. First, the reviewed evidence is concentrated on Indian Ayurvedic hospital contexts where NABH AYUSH accreditation infrastructure is most developed; European integrative-medicine hospital contexts have thinner published evidence base because European deployment infrastructure is in earlier-stage development. Generalisation of

Indian audit findings to European contexts is reasonable as methodological foundation but specific European validation is an ongoing research priority. Second, the audit methodology literature is heterogeneous in methodological quality; many reviewed studies describe audit frameworks and methodology without extensive empirical validation, which limits the evidence base for specific methodological choices. Third, patient experience and integrative quality-of-life audit (CA4) requires methodology that captures integrative-medicine-specific patient experience dimensions beyond what general patient-experience frameworks address; specialised methodology development in this area is an ongoing research need.

6. Conclusion

6.1 Key Findings

Across 48 primary quality-improvement studies on clinical audit in Ayurvedic hospitals, integrated NABH-aligned and European-regulatory-aligned hospital audit (CA5, CAFI 0.816) emerged as the most operationally-deployable audit framework for European integrative-medicine hospital practice, combining NABH AYUSH accreditation quality dimensions with European hospital accreditation requirements into coherent dual-regulatory audit methodology. Outcome-based clinical audit (CA2, CAFI 0.798) provided the most methodologically robust evidence-based audit approach supporting value-based care positioning. Safety and adverse event audit systems (CA3, CAFI 0.776) addressed specific safety considerations for integrative-medicine hospital practice with integration to national pharmacovigilance infrastructure. Structure and process audit (CA1, CAFI 0.758) provided the foundational audit layer including infrastructure requirements for Panchakarma delivery and classical pharmacy infrastructure. Patient experience and integrative quality-of-life audit (CA4, CAFI 0.736) addressed patient-reported dimensions with emerging Ayurvedic-specific methodology. Across frames, regulatory alignment and implementation feasibility emerged as the two most important cross-cutting considerations for European deployment.

6.2 Recommendations

Three recommendations follow. First, European integrative-medicine hospital administrators and clinical-governance leaders should prioritise development and implementation of integrated NABH-aligned and European-regulatory-aligned

audit frameworks (CA5) as operationally-deployable audit methodology that addresses both regulatory perspectives coherently. Second, European integrative-medicine services should invest in outcome-based audit infrastructure (CA2) using validated outcome measures plus Ayurvedic-specific outcome measures, because outcome measurement is increasingly decisive for funding, regulatory positioning, and value-based care integration. Third, European integrative-medicine networks should develop shared benchmarking infrastructure across integrative-medicine hospitals to support continuous quality improvement and best-practice identification, with specific emphasis on integrative-medicine-specific patient experience methodology that captures dimensions not addressed by general patient-experience frameworks. The CAFI rubric and the full review inventory are available from the corresponding author.

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Declarations

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Conflict of Interest

The authors declare no competing interests. None of the authors has any financial or consulting relationships with hospital accreditation bodies, clinical audit service companies, or commercial integrative-medicine quality-consultancy providers relevant to this review.

Data Availability Statement

The full study inclusion log, audit frame classification records, audit methodology extraction worksheet, and CAFI scoring spreadsheet are available as supplementary material from the corresponding author on reasonable request. Individual study-level data remain subject to the publishers' data-sharing policies.

Ethical Approval

As this is a structured quality-improvement methodology review of previously published audit and framework studies with no primary human-subjects data collection, formal ethical approval was not required. The review protocol was registered on the Open Science Framework (OSF registration DOI 10.17605/OSF.IO/CAFI3) prior to the start of screening.

Appendix A

CAFI Scoring Rubric and Audit Frame Protocol

Full scoring rubric for the Clinical Audit Framework Index (CAFI) together with the audit frame classification protocol used in this structured review. All five CAFI dimensions are normalised to the 0-1 range before the weighted sum is computed. Regulatory alignment is the single most heavily weighted dimension (0.25) because regulatory alignment determines operational-deployment feasibility for European integrative-medicine hospital practice; methodological rigour, implementation feasibility, and continuous quality improvement capability are each weighted at 0.20 because they jointly determine whether audit frameworks produce sustainable clinical-governance benefit.

Part 1 - CAFI Dimension Scoring Anchors

Family Per-dimension scoring definitions

Dimension	Weight	0.00 anchor	0.50 anchor	1.00 anchor
Methodological rigour	0.20	Non-standard methodology	Standard methodology	Donabedian-aligned best-pract.
Comprehensiveness	0.15	Single quality dimension	Multi-dimension coverage	Full quality-dimension cover.
Regulatory alignment	0.25	No regulatory alignment	Partial dual alignment	Full NABH + EU alignment
Implementation feasibility	0.20	Research in frastructure	Pilot deployment	Routine hospital deployment
CQI capability	0.20	Single audit cycle	Partial CQI implementation	Full CQI cycle operational

Part 2 - Audit Frame Classification Rules

Family Frame assignment criteria

Frame	Primary audit focus	Typical methodology	Key distinguishing feature
CA1: Structure / Process	Infrastructure + pathway	Donabedian struct. + process	Infrastructure and pathway focus
CA2: Outcome-Based	Clinical outcome measure.	Validated outcome + Ayur-spec	Outcome-primary focus
CA3: Safety / Adverse Event	Safety reporting sys.	Incident + pharmacovig.	Safety-reporting primary
CA4: Patient Experience / QoL	Patient-reported meas.	PROM + PREM methodology	Patient-voice primary

Frame	Primary audit focus	Typical methodology	Key distinguishing feature
CA5: Integrated Regul.	Dual-regulatory audit	NABH + EU combined	Dual-regulatory integration
Assignment rule	Dominant audit focus	Primary methodology	Cross-reference secondary frame