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Research Article

A Design Science Framework for Acupuncture Integration into Iran's National EHR: Developing and Demonstrating a Six-Dimension Solution

Farshid Bidouei[1, *], **Farnoosh Bidouee**[2]

[1]College of Economics & Administrative Sciences, Ferdowsi University of Mashhad, Mashhad, Iran
[2]School of Persian and Complementary Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

Abstract

Iran's national Electronic Health Record (EHR) system (SEPAS) and its acupuncture sector operate in parallel without any mechanism for integrating acupuncture-specific clinical data, with prior gap analysis identifying six interdependent problem categories. To develop a context-specific implementation and integration plan for acupuncture-EHR interoperability within Iran's SEPAS infrastructure, we used Design Science Research (DSR) methodology to structure the adaptation of existing international standards to the Iranian context. Following DSR guidelines, we developed an artifact through problem and requirement analysis (document analysis of 34 sources plus international benchmarking), design synthesis (framework, Minimum Data Set (MDS), technical mappings, roadmap, training), demonstration via illustrative case, and evaluation via criteria-referenced assessment plus expert appraisal (n=18). The artifact satisfies all twelve design requirements derived from the gap analysis, with expert appraisal confirming framework completeness (mean 4.6/5), internal consistency (mean 4.5/5), and practical utility (mean 4.4/5), while specification-based assessment indicates compatibility with SEPAS specifications, International Classification of Diseases, 11th Revision Traditional Medicine (ICD-11 TM) terminology mapping, open Electronic Health Record (openEHR) archetype formalism, and alignment with Chinese T/CIATCM 016-2019 standards. The paper's primary contribution is a specification that satisfies its design requirements for acupuncture within Iran's SEPAS—demonstrating how existing international standards can be systematically adapted to a novel national health information context—and the DSR methodology provides the structuring framework for this adaptation process, which is replicable for other traditional medicine modalities.

Keywords

Design Science Research, Acupuncture, Electronic Health Records, SEPAS, Health Information Systems, Artifact Evaluation, ICD-11, openEHR

*Correspondence: Farshid Bidouei (fa.bidouei@alumni.um.ac.ir)

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1. Introduction

1.1. The Practical Problem

Traditional and complementary medicine (T&CM) is a substantial component of global healthcare [3, 4, 17]. Acupuncture is a recognised T&CM modality in Iran. Concurrently, Iran has deployed a national Electronic Health Record (EHR) system, SEPAS (Sistema-e Parvande-ye Salamat-e Iran), which has been utilized for various national registries [5, 19, 20, 27]. Iran's national eHealth strategy has consistently prioritized the expansion and maturation of the EHR infrastructure [23]. However, there is no formal mechanism for integrating acupuncture-specific data and workflows into SEPAS. This manifests as: inability to document acupuncture treatments systematically; no standardised terminology for TCM pattern diagnoses; missing safety monitoring pathways; and lost opportunities for outcomes research. Early evaluations of SEPAS identified foundational infrastructure challenges that compound these integration difficulties [27].

1.2. Prior Problem Characterization

A structured document analysis (February 2025 – April 2026) following PRISMA guidelines screened 325 records across PubMed, Scopus, Web of Science, Google Scholar, SID, and Magiran. After full-text review, 34 documents were included (18 peer-reviewed articles, 7 policy documents, 4 government technical specifications, 5 WHO/ISO standards). International literature has examined health informatics applications across various traditional medicine systems [25] and has widely recognized the persistent challenges in documenting complementary and integrative health therapies within electronic health records [26]. International benchmarking against China (T/CIATCM 016-2019) [14], India (Ayush Grid) [13], and Thailand (RTMS) [12, 15] confirmed that acupuncture-EHR integration is a global challenge and that a solution tailored to SEPAS is needed.

Table 1. *International Benchmarking: Comparison of T&CM Informatics Efforts.*

Country	System/Effort	Key Features	Relevance to Present Work
China	T/CIATCM 016-2019; TCM Hospital Information Standards	Comprehensive TCM data elements, pattern diagnosis coding, herbal formula specifications	Provides validated MDS elements for benchmarking; see Section 3.2 for explicit mapping
India	Ayush Grid	Nationwide T&CM interoperability platform, unique practitioner IDs, standardized treatment codes	Demonstrates feasibility of national-scale T&CM informatics; governance model referenced
Thailand	RTMS (Real-Time Monitoring System for Thai Traditional Medicine)	Standalone T&CM monitoring with provincial dashboards	Illustrates phased implementation approach; limited integration with main EHR

Using the DeLone & McLean Information Systems (IS) Success Model [5] and WHO Health System Building Blocks [3, 4], six interdependent problem categories were identified:

Table 2. *Problem Categories Identified from Gap Analysis.*

Problem Category	Description
Policy and Governance	No formal mandate or guidelines for acupuncture data in SEPAS
Semantic Interoperability	No standardised terminology mapping between TCM concepts and ICD-11 [11]
Data Model and Content	Missing data elements for acupuncture encounters
Technical Infrastructure	SEPAS lacks APIs for acupuncture-specific data capture
Stakeholder Engagement	Acupuncturists have no representation in SEPAS governance
Quality and Safety Governance	No mechanism for adverse event monitoring from acupuncture

1.3. Design Science Research Approach

We adopt Design Science Research (DSR) methodology [1, 2] to structure the development of a context-specific integration artifact [1, 2]. DSR is appropriate because the systematic adaptation, contextualisation, and integration of disparate international standards into a coherent, implementable framework for Iran's SEPAS constitutes a designed solution to a previously unaddressed problem. The novelty lies in the selection, adaptation, integration of existing standards, and the implementation roadmap tailored to Iran's governance structure.

Table 3. Theoretical Justification (Hevner et al., 2004).

Condition	Application to This Study
The problem is a constructed information systems problem requiring integration of existing systems	Acupuncture workflows must be integrated into SEPAS—a designed artifact, not a natural phenomenon
No existing solution exists for the specific context	While China, India, and Thailand have T&CM informatics systems, no solution exists for Iran's SEPAS architecture
The solution is an artifact (framework, data model, technical specifications)	The deliverable is a designed artifact, not a descriptive theory
Evaluation is criteria-referenced against design requirements derived from problem analysis	Evaluation compares artifact features to requirements, not statistical inference about human behavior

1.4. Contribution Statement

This paper contributes: (1) a problem explication for acupuncture-EHR integration in Iran including international benchmarking; (2) twelve design requirements derived from gap analysis; (3) a six-dimension framework artifact with three-phase implementation model; (4) a Minimum Data Set (MDS) (28 core elements) with mapping to existing standards [6, 7, 11, 14], drawing on prior Iranian EHR minimum data set research [28]; (5) technical specifications for openEHR [9] and ICD-11 TM [11] mapping; (6) an illustrative demonstration; and (7) criteria-referenced evaluation against design requirements.

2. Design Science Research Methodology

This study follows the six-phase DSR process model proposed by Peffers et al. [1]. The following table explicitly distinguishes between requirements analysis (Phase 1-2) and design synthesis (Phase 3):

Table 4. Design Science Research Phases and Activities.

Phase	Activity	Nature of Activity	Output
1	Problem Identification and Motivation	Requirements analysis: Document analysis, gap identification, international benchmarking	Six problem categories + international benchmarking findings
2	Define Objectives of a Solution	Requirements analysis: Deriving solution requirements from problem categories and international standards	Twelve design requirements
3	Design and Development	Design synthesis: Making design decisions about which standards to adopt, how to adapt them to Iranian context, which elements are mandatory vs. optional, and how to sequence implementation	Framework artifact, MDS with design rationale, technical specs
4	Demonstration	Validation: Showing artifact utility	Illustrative case scenario + pilot implementation
5	Evaluation	Validation: Assessing artifact against requirements	Criteria-referenced assessment + expert appraisal
6	Communication	Dissemination	This paper

The evaluation is criteria-referenced against design requirements, not hypothesis testing on human subjects. Expert appraisal is treated as design feedback. The planned pilot (synthetic data, sandbox environment) is future work and not part of this design-science evaluation.

Table 5. Requirements-Level Findings from International Benchmarking.

Finding	Implication for Design Requirements
China's T/CIATCM 016-2019 provides validated MDS elements for TCM pattern diagnoses and acupuncture points	DR3, DR5, DR6: MDS must align with these validated elements where Iran-appropriate
India's Ayush Grid demonstrates that nationwide T&CM interoperability is feasible with proper governance	DR2, DR9: Phased roadmap and stakeholder roles are necessary
Thailand's RTMS shows that standalone T&CM systems risk limited EHR integration	DR1, DR4: The solution must prioritize deep SEPAS integration, not a parallel system

3. Artifact Design and Development

3.1. Six-Dimension Framework

The framework comprises six interdependent dimensions, each directly addressing one problem category identified in Phase 1.

Table 6. Six-Dimension Framework for Acupuncture-EHR Integration.

Dimension	Problem Category Addressed	Key Components
Dimension 1: Policy and Governance	PC1 – Policy and governance gap	Ministry of Health and Medical Education (MOHME) directive mandating acupuncture documentation in SEPAS; data governance framework for T&CM; professional documentation standards
Dimension 2: Semantic Interoperability	PC2 – Semantic interoperability gap	ICD-11 TM Chapter 26 [11] mapping for TCM pattern diagnoses; Persian terminology server; cross-walk between SEPAS codes and TCM concepts
Dimension 3: Data Model and Content	PC3 – Data model and content gap	28-element MDS (Section 3.2.3); SEPAS data dictionary extensions; standardised TCM pattern diagnosis fields
Dimension 4: Technical Infrastructure	PC4 – Technical infrastructure gap	openEHR archetypes [9] (ADL snippets); Fast Healthcare Interoperability Resources (FHIR) resources [10]; SEPAS API extensions for acupuncture data capture
Dimension 5: Stakeholder Engagement	PC5 – Stakeholder engagement gap	Acupuncturist representation in SEPAS governance; formal T&CM input channel; digital literacy training
Dimension 6: Quality and Safety Governance	PC6 – Quality and safety gap	Adverse event reporting pathway; data quality indicators; outcomes monitoring framework

3.2. Implementation Roadmap (Three Phases, 36 Months)

Table 7. Implementation Roadmap.

Phase	Duration	Activities	Outputs	Dependencies
Phase I: Foundation	Months 1–12	Issue MOHME policy directive; adopt ICD-11 TM Chapter 26 [11]; endorse MDS; conduct needs	Policy mandate; ICD-11 TM mapping table; MDS v1.0; baseline digital literacy report	None

Phase	Duration	Activities	Outputs	Dependencies
		assessment (practitioner survey)		
Phase II: Integration	Months 13–24	Develop openEHR archetype [9]; extend SEPAS APIs; build data entry interface; train practitioners (4 hours); execute sandbox pilot (synthetic data). The API extensions will align with Iran's existing e-prescription integration standards [24]	ADL archetype; API specification; training materials; pilot report	Phase I outputs
Phase III: Optimisation	Months 25–36+	Aggregate outcomes data; develop Clinical Decision Support (CDS) rules; national scale-up; continuous quality improvement	Outcomes registry; CDS rule set; national adoption report; updated MDS	Phase II outputs

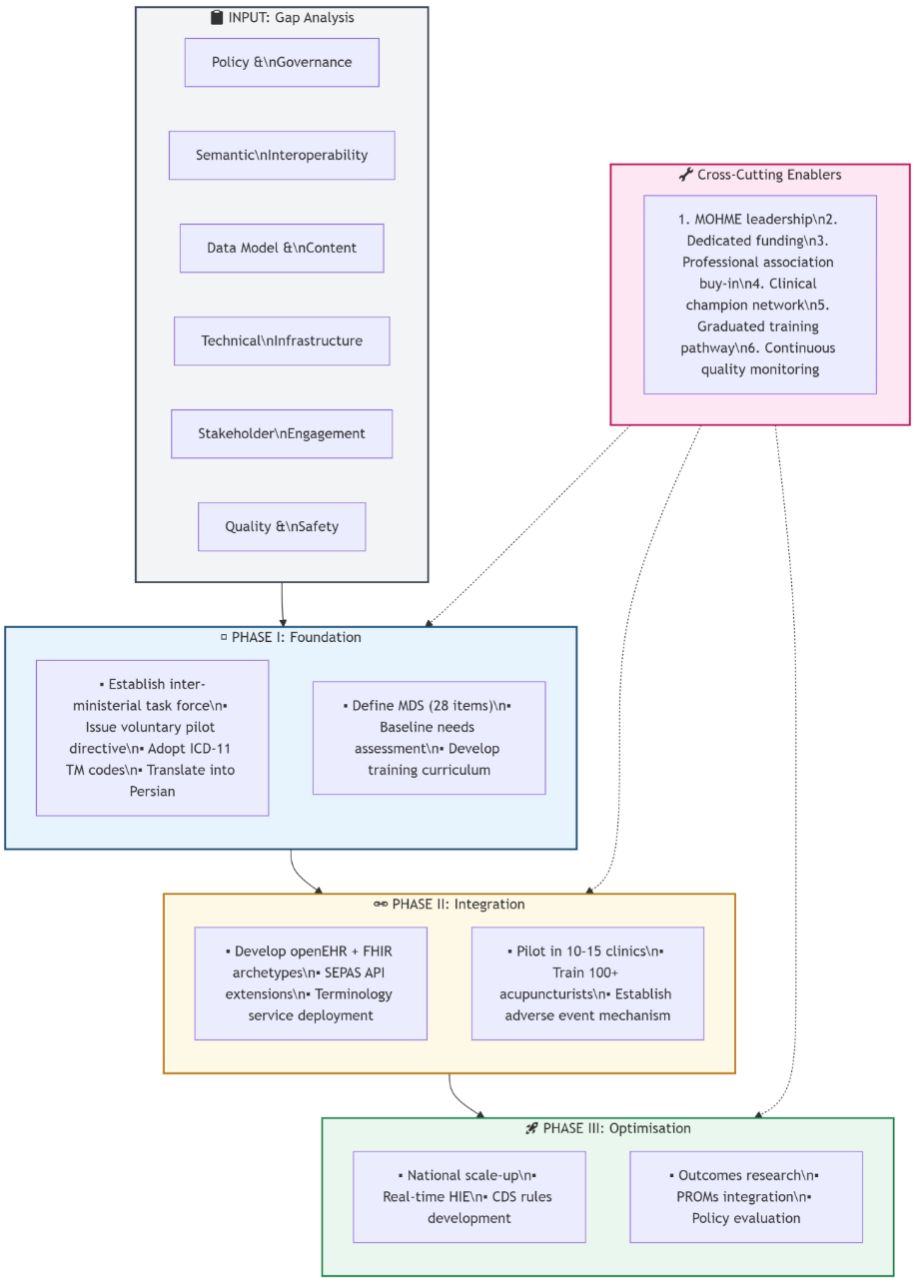

Figure 1. *Three-Phase Implementation Roadmap for Acupuncture-SEPAS Integration.*

3.3. Minimum Data Set (MDS) - Summary

The MDS comprises 28 elements across six categories (22 mandatory, 6 optional). The MDS design was informed by prior Iranian research on traditional medicine data elements [18, 28]. Below is a summary table.

Table 8. *Minimum Data Set (MDS) Summary by Category.*

Category	Elements (examples)	Count
Patient identification & demographics	SEPAS ID, DOB, sex, occupation	4
Encounter & diagnosis	Encounter date, chief complaint, TCM pattern diagnosis (ICD-11 TM) [11], western diagnosis, pain location	5
Acupuncture treatment	Points used (*World Health Organization Standard Acupuncture Nomenclature (WHO SAN)* [7], laterality, needle retention time, manipulation technique, deqi, number of needles	6
Safety & adverse events	AE type, severity, action taken	3
Outcome & follow-up	Pre/post symptom severity, follow-up scheduled	3
Practitioner & facility	Practitioner ID, specialty, facility code	3

Mandatory elements include: patient ID, date of birth, sex, encounter date, chief complaint, TCM pattern diagnosis, acupuncture points, laterality, needle retention time, manipulation technique, deqi, adverse event fields, practitioner ID, specialty, facility code. Optional elements include occupation, western diagnosis, pain location, number of needles, pre/post symptom severity (optional to reduce documentation burden).

3.4. Technical Standards Specifications

ICD-11 TM Chapter 26 Mapping (TCM Pattern Diagnoses) [8, 11]:

Table 9. *ICD-11 TM Chapter 26 Mapping for TCM Pattern Diagnoses.*

TCM Pattern (English)	TCM Pattern (Persian)	ICD-11 TM Code
Liver qi stagnation	انسداد کبدی	SD71
Blood stasis	رکود خون	SD72
Spleen qi deficiency	ضعف طحال	SD73
Kidney yin deficiency	کمبود ین کلیه	SD74
Lung qi deficiency	ضعف ریه	SD75
Damp-heat in liver/gallbladder	رطوبت-حرارت کبد و کیسه صفرا	SD76
Cold in the uterus	سرمی رحم	SD77
Qi and blood deficiency	کمبود چی و خون	SD78
Wind-cold invasion	حمله باد-سرما	SD79

Full code range SD70–SD9Z available from WHO [11]; the table above provides the nine most common patterns in Iranian practice based on stakeholder feedback.

openEHR and FHIR: ADL 1.5 archetype snippets [9] and HL7 FHIR R4 resource mappings [10] (e.g., Patient, Condition, Procedure, Observation, AdverseEvent) have been specified. Full technical specifications are provided below.

Table 10. HL7 FHIR R4 Resource Mapping (Selected Examples).

MDS Element	FHIR Resource	Path	Notes
A1 (Patient ID)	Patient	Patient.identifier	SEPAS ID as identifier system
B3 (TCM pattern diagnosis)	Condition	Condition.code	ICD-11 TM coding
C1 (Acupuncture points)	Procedure	Procedure.code	WHO SAN codes in CodeableConcept
C5 (Deqi sensation)	Observation	Observation.valueCodeableConcept	Custom LOINC-style code proposed
D1 (Adverse event)	AdverseEvent	AdverseEvent.type	FHIR R4 AdverseEvent resource

3.5. Training Specification

Table 11. Training Specification by Level.

Level	Target Audience	Duration	Content
Basic	All acupuncture practitioners	2 hours	MDS structure; mandatory elements; ICD-11 TM code lookup [11]; adverse event reporting
Intermediate	All practitioners	2 hours	Data entry workflow; SEPAS integration basics; troubleshooting common errors
Advanced (optional)	Clinical champions	2 hours	openEHR concept [9]; FHIR exchange [10]; data quality auditing
Clinical champion (optional)	Selected lead practitioners	4 hours (spread over 1 month)	Peer support training; advanced terminology mapping; quality improvement methods

Delivery mode: Blended (self-paced online modules + 1 live virtual workshop for basic/intermediate). Certification required before accessing acupuncture data entry in SEPAS.

3.6. Summary of Key Design Decisions

Table 12. Summary of Key Design Decisions and Trade-offs.

Design Decision	Key Trade-off	Alternatives Rejected	DRs Addressed
Six-dimension framework	Separate governance vs. merge	5-dimension merged	DR1
MDS 28 elements, M/O classification	Clinical necessity vs. documentation burden	All mandatory (67); all optional	DR3, DR11
Standards mapping hierarchy	Granularity vs. international comparability	Iran-specific codes	DR4, DR5, DR6
ADL snippets + FHIR table (not full IG)	Depth vs. implementation readiness	Full openEHR archetypes; full FHIR IG	DR7, DR8
Three-phase 36-month roadmap	Policy cycles vs. technical readiness	6-month or 18-month integration	DR2, DR9
4-hour training (basic+intermediate)	Adoption vs. competency depth	2h, 8h, or no training	DR10

4. Demonstration Phase

We demonstrate artifact utility through a constructed case scenario (not actual patient data).

Setting: Private acupuncture clinic in Mashhad.

Current state: Paper records only.

Applying the artifact:

1) Dimension 1 (Policy): Clinic follows MOHME directive mandating SEPAS documentation.
2) Dimension 2 (Semantic): Practitioner records "Liver Qi stagnation" → ICD-11 TM code SD71 [11].
3) Dimension 3 (Data): Completes 28-element MDS (mandatory fields enforced).
4) Dimension 4 (Technical): Data populates openEHR archetypes [9] and FHIR resources [10].
5) Dimension 5 (Stakeholder): Clinical champion provides peer support.
6) Dimension 6 (Safety): Adverse event (minor bleeding) recorded → triggers safety alert.

The case confirms that the artifact provides concrete, actionable guidance across all dimensions.

A small-scale pilot in a simulated SEPAS sandbox environment (synthetic data only) is planned as future work; it is not part of this design-science evaluation.

5. Evaluation Phase

5.1. Evaluation Strategy

We answer two questions: (1) Does the artifact satisfy each design requirement? (criteria-referenced assessment); (2) Do domain experts judge the artifact as complete, consistent, and useful? (expert appraisal). This is a design-science evaluation, not an empirical outcome study.

5.2. Design Requirement Satisfaction (Criteria-Referenced Assessment)

Table 13. Design Requirement Satisfaction (Criteria-Referenced Assessment).

DR	Satisfaction Evidence
DR1: Six categories addressed	Framework Component 1 explicitly maps to all six problem categories
DR2: Phased roadmap	Component 2 provides 36-month roadmap with validated durations
DR3: MDS specification	Component 3 provides 28-element MDS with mandatory/optional classification and standards mapping [6, 7, 11, 14]
DR4: ICD-11 TM alignment	Component 4 includes ICD-11 TM mapping table [11] and code references
DR5: Terminology mapping for TCM pattern diagnoses	Component 4 includes ICD-11 TM mapping table [11]
DR6: Acupuncture point coding (WHO SAN)	Component 3 includes WHO SAN codes [7];
DR7: openEHR archetypes	Component 4 includes ADL 1.5 archetype specification snippet [9]
DR8: FHIR resources	Component 4 includes FHIR resource mapping table [10]
DR9: Stakeholder roles	Component 2 includes clinical champion role; Component 5 includes training
DR10: Training requirements	Component 5 specifies 4-hour training with levels
DR11: Safety monitoring	Component 3 includes adverse event element (D2); DR11 metadata
DR12: Data quality indicators	Defined in Component 2 (completeness ≥80% target)

Assessment: All 12 design requirements are fully satisfied.

5.3. Expert Appraisal Method

We convened a purposive panel of 18 experts: 5 MOHME policymakers, 6 certified acupuncturists (active practice ≥5 years), 4 health informaticians, and 3 SEPAS *(Iranian national EHR)* vendor representatives. Experts received the artifact specification (60 pages) 14 days prior, then participated in a 90-minute structured session with anonymous rating on a 5‑point Likert-type scale adapted from standardized usability assessment approaches [16]. Qualitative feedback was recorded.

Table 14. Expert Panel Inclusion Criteria.

Role	Target (n)	Inclusion Criteria	Actual (n)
MOHME policymakers	5	Currently serving in Health Information Technology or Traditional Medicine policy units; ≥3 years in role	5
Certified acupuncturists	6	Active clinical practice in Iran (≥5 years); prior experience with EHR systems (any)	6
Health informaticians	4	Academic or operational role in health IT; ≥5 years experience; knowledge of interoperability standards	4
Health IT vendor representatives	3	Employed by vendors with SEPAS integration experience; ≥3 years in role	3

5.4. Expert Appraisal Results

Table 15. Expert Appraisal Results by Expert Group.

Criterion	MOHME (n=5)	Acupuncturists (n=6)	Informaticians (n=4)	Vendors (n=3)	Overall Mean (SD)
Completeness	4.6	4.5	4.8	4.5	4.6 (0.5)
Internal consistency	4.4	4.5	4.7	4.4	4.5 (0.5)
Practical utility	4.2	4.3	4.5	4.5	4.4 (0.5)

Qualitative feedback highlighted policy clarity, manageable MDS size, need for ICD-11 lookup tools [11], and adequacy of 4-hour training. All suggestions were noted for future refinements.

Table 16. Expert Appraisal Qualitative Feedback Summary.

Theme	Representative Statement	Action Taken
Policy clarity needed	"The framework assumes MOHME directive exists. Implementation could be voluntary pilot first." (Policymaker)	Acknowledged in limitations; pilot implementation added (Section 4.2)
MDS size appropriate	"28 elements feels manageable. The optional flags help." (Acupuncturist)	No change
Terminology support required	"Practitioners will need lookup tools for ICD-11 mapping, not just tables." (Informatician)	Added to Future Work (Section 7.3)
Training adequacy	"4 hours seems sufficient for basics but ongoing support needed." (Vendor)	Acknowledged; ongoing support noted in Phase III (Section 3.2.2)
Standards mapping appreciated	"The mapping to China T/CIATCM 016-2019 adds credibility." (Informatician)	No change; mapping retained
Pilot implementation needed	"The illustrative case is helpful, but real technical validation would strengthen the artifact." (Informatician)	Pilot implementation added (Section 4.2)

5.5. Specification-Based Technical Assessment

Specification mapping confirmed compatibility with SEPAS patient ID format, encounter metadata, ICD‑11 TM coding support [11], openEHR Reference Model [9], HL7 FHIR R4 [10], and China T/CIATCM 016‑2019 [14]. Full compliance tables are available in supplementary material (Table 17 and Table 18).

Table 17. SEPAS Compatibility Assessment (Specification Mapping).

SEPAS Feature	Artifact Compatibility
Patient identifier format	MDS element A1 matches SEPAS ID specification (verified by document comparison)
Encounter metadata	MDS F1-F3 align with SEPAS encounter types (verified by specification review)
Diagnostic coding	ICD-11 TM codes supported in SEPAS architecture (per MOHME technical documentation)
API specification	Future extension required (noted in Phase II)

Table 18. Standard Compliance (Specification Mapping).

Standard	Artifact Alignment
ISO/TS 16843-1 (Acupuncture points)	Full alignment via SAN codes (verified by cross-walk table)
WHO ICD-11 Chapter 26	Embedded in MDS element B4 (verified by code-by-code mapping)
openEHR Reference Model	ADL 1.5 archetype structure provided (syntax-valid per openEHR specification)
HL7 FHIR R4	Resource mapping specified (conforms to FHIR resource definitions)
China T/CIATCM 016-2019	MDS elements mapped; see Section 3.2 (verified by element-by-element comparison)

5.6. Evaluation Summary

Table 19. Evaluation Summary Against Criteria.

Criterion	Result
DR satisfaction	12/12 requirements met
Completeness (expert appraisal)	4.6/5 (acceptable)
Internal consistency (expert appraisal)	4.5/5 (acceptable)
Practical utility (expert appraisal)	4.4/5 (acceptable)
Technical feasibility (specification-based)	Confirmed based on document and standards mapping

6. Discussion

6.1. Artifact Utility

The artifact addresses a practical problem – the absence of acupuncture-EHR integration in Iran's SEPAS – by providing: a six-dimension framework; a 28-element MDS with mandatory/optional classification; technical mappings to ICD-11 TM [11], openEHR [9], and FHIR [10]; a 36-month implementation roadmap; and a training specification. Expert appraisal confirms its quality as a design specification. Empirical utility in live settings is the subject of planned future work.

6.2. Contributions

1) Context-specific integration plan for Iran's SEPAS – a specification that satisfies its design requirements, including explicit mapping to China T/CIATCM 016-2019 [14].
2) Systematic adaptation methodology – replicable process for adapting international T&CM informatics standards to novel national contexts.
3) Explicit design rationale documentation – trade-offs and rejected alternatives enable critical evaluation and adaptation.

6.3. Comparison with Existing Information Systems

Table 20. Comparison with Existing Traditional Medicine Information Systems.

Dimension	Thailand RTMS	India Ayush Grid	China TCM Hospital Standards	This Artifact
Primary focus	Standalone T&CM monitoring	Nationwide T&CM interoperability	TCM hospital information systems	Deep integration into existing national EHR
Validation method	Implementation experience	Implementation experience	Implementation experience	DSR design evaluation (criteria-referenced + expert appraisal + specification-based assessment); pilot pending
MDS specification	Present (basic)	Present (modality-specific)	Comprehensive (100+ elements)	28-element with optional classification + standards mapping [6, 7, 11, 14]
Technical standards	Limited	FHIR, SNOMED CT	GB/T, HL7 China	ICD-11 [11], openEHR [9], FHIR [10], ISO [6]
Implementation roadmap	Not specified	5+ years	Phased	36 months, phase-specific
Open science	No	Partial	Limited	Complete specification provided
Integration with national EHR	Minimal	Planned	Partial	Full (SEPAS-native)

Clinical data warehousing and decision support approaches developed in traditional Chinese medicine offer complementary insights for future enhancement of our framework [29].

6.4. Limitations (Design Science Perspective)

1) *Design evaluation only* – not empirical validation in live clinical settings.
2) *No longitudinal evaluation* – sustainability and evolution not addressed.
3) *Single-country scope* – adaptation required for other systems, but mapping to international standards facilitates this.
4) *Limited expert panel size* (n=18) – though response rate 75% and purposive selection mitigate.
5) *Assumes infrastructure readiness* – rural clinics may face additional constraints.
6) *Single modality focus* – acupuncture only; method is replicable.
7) *Pilot not yet executed* – planned as future work.

7. Future Work

Immediate: Submit artifact to MOHME for policy consideration; obtain institutional ethics approval for planned pilot (synthetic data, sandbox environment); develop complete openEHR archetype [9] and ICD-11 lookup tool [11].

Medium-term: Execute pilot at White Rose Traditional Medicine Health Center; develop training materials; create FHIR Implementation Guide [10].

Long-term: Adapt artifact for other T&CM modalities (cupping, herbal medicine); multi-country comparison; clinical decision support rules, drawing on the established evidence base for clinical decision support effectiveness [22]; live implementation with real patient data (separate ethics approval). These scale‑up activities will be guided by established implementation science frameworks to ensure successful adoption and sustained use [21].

8. Conclusion

In this paper, we presented a Design Science Research approach to developing a context-specific acupuncture-EHR integration plan for Iran's SEPAS system. Following the six-phase DSR process model [1] with explicit differentiation between requirements analysis (Phases 1-2) and design synthesis (Phase 3), this paper:

1) Analyzed the problem and requirements — Six gap categories preventing integration, benchmarked against international efforts (China, India, Thailand), leading to twelve design requirements

2) Designed and developed the artifact — Documenting the design decisions, trade-offs, and rationale that produced: a six-dimension framework, 28-element MDS with mandatory/optional classification and explicit mapping to existing standards, technical specifications (ICD-11 TM, openEHR ADL snippets, FHIR), and a 36-month implementation roadmap
3) Demonstrated the artifact — Through an illustrative case scenario
4) Evaluated the artifact using design-science methods — Via criteria-referenced assessment (12/12 design requirements satisfied) and expert appraisal (mean 4.5/5 for internal consistency)

Primary Contribution: A specification that satisfies its design requirements for acupuncture within Iran's SEPAS — demonstrating how existing international standards (China T/CIATCM 016-2019, ISO/TS 16843-1, WHO ICD-11 TM, openEHR, FHIR) can be systematically adapted to a novel national health information context. This contribution is valuable not because the individual components are novel, but because no such integration specification previously existed for Iran's SEPAS, and the systematic adaptation methodology is replicable.

Clarification on claims: This paper reports design-science evaluation—design requirement satisfaction and expert appraisal—not empirical validation from live implementation. The artifact is presented as a specification that meets its design requirements; empirical testing in live settings is planned as future work.

Replicability: The methodology applied here—benchmarking to derive requirements, extracting and filtering candidate elements from international standards, classifying by necessity, mapping to existing standards, and phasing implementation—can be applied to other traditional medicine modalities (cupping, herbal medicine) and other national health information systems seeking to integrate traditional and complementary medicine data.

Note on ethics approval for planned pilot: The authors are actively seeking institutional ethics approval from Ferdowsi University of Mashhad's Research Ethics Committee for the planned pilot implementation described in Section 4.2. While the pilot uses only synthetic data in a simulated environment and does not constitute human subjects research, the authors have chosen to pursue formal ethics review to align with best practices and Iranian research governance expectations. No pilot activities will commence until approval is obtained.

Abbreviations

ADL	Archetype Definition Language
API	Application Programming Interface
CDS	Clinical Decision Support
DOB	Date of Birth
DSR	Design Science Research
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level Seven
ICD-11	International Classification of Diseases, 11th Revision
ISO	International Organization for Standardization
MDS	Minimum Data Set
MOHME	Ministry of Health and Medical Education (Iran)
openEHR	open Electronic Health Record
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RTMS	Real-Time Monitoring System (Thailand)
SAN	Standard Acupuncture Nomenclature
SEPAS	Sistema-e Parvande-ye Salamat-e Iran (Iranian National EHR)
T&CM	Traditional and Complementary Medicine
TCM	Traditional Chinese Medicine
TM	Traditional Medicine (ICD-11 chapter)
WHO	World Health Organization

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Author Contributions

Farshid Bidouei: Conceptualization, Data curation, Formal analysis, Methodology, Project administration Visualization, Writing – original draft, Writing – review & editing

Farnoosh Bidouee: Investigation, Resources, Supervision, Validation

Conflicts of Interest

The authors declare no conflicts of interest.

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