

Hospital Readiness to Integrate Medical Devices and Health Information Systems

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Abstract

Hospital digital transformation requires integrating hospital information systems, electronic health records, networks, data, and medical devices into governed clinical processes. However, digital maturity and interoperability models do not incorporate clinical engineering and health technology management capabilities to the same extent. This study presents a rapid scoping review based on the Scopus database and a conceptual synthesis whose contribution is an integrated framework for assessing hospital readiness to integrate medical devices with hospital information systems. Ninety-eight records were identified; 54 full texts were assessed, and 38 studies were included. Structured extraction was synthesized using a crosswalk of ten domains coded as absent (0), partial (1), or strong (2). Interoperability and standards showed strong evidence in 29/38 studies, information technology infrastructure and architecture in 24/38, and governance and organization in 23/38. Clinical Engineering and Health Technology Management (CE/HTM) was coded as central in fewer studies (7/38) and was absent in 25/38. Only one study strongly integrated clinical engineering and health technology management, information technology infrastructure, interoperability, governance, and clinical workflow simultaneously. These results support a framework built on four capabilities: institutional readiness, cyber-physical integration, interoperability and information, and clinical-operational integration. Two further dimensions (security/risk and people/culture) are transversal in the framework, with the external ecosystem serving as context. A preliminary operationalization comprises 21 scoring criteria. Readiness in the cyber-physical, interoperability, and data governance layers provides hospitals with the conditions to verify the provenance, quality, and traceability of clinical data. That verification comes before the data is fed into diagnostic models and analytics. Making such readiness explicit supports biological modeling and advanced data analysis rather than replacing them. At present, this proposal remains at the conceptual level and requires content validation, piloting, and reliability testing before any comparative use.

Keywords

Hospital readiness, Interoperability, Medical devices, Clinical engineering, HTM, HIS, EHR, Digital maturity, CE-IT integration

1. Introduction

Hospitals operate as sociotechnical systems, where technical infrastructure and clinical practice depend on each other. Electronic health records (EHRs), hospital information systems (HIS), departmental systems, data platforms, networks, and medical devices all must exchange information securely and in ways that are functional for the clinical workflow. Two families of assessment instruments address this setting: digital maturity models and interoperability or networking models [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16]. They complement each other, but their assessment of connected medical technology can be limited.

Clinical Engineering and Health Technology Management (CE/HTM) work at two levels. At the system level, it covers inventory, traceability, commissioning, lifecycle, and maintenance. At the system level, it covers interface validation, medical IT network risk, and CE-IT coordination. The literature

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on healthcare 4.0, predictive maintenance, cyber-physical systems, device data standardization, and IEC 80001-1 provide specific evidence for these capabilities [17, 18, 19, 20, 21, 22, 23]. However, these contributions often remain separate from institutional models of readiness.

The ambition to translate raw clinical data into rigorous diagnostic information with minimal information loss is often posed as a modeling and analytical problem. However, data fidelity depends as much on the chain of custody as on the algorithm that interprets data. It starts with the medical device, passes through the network and the interfaces that transport it, and ends with the semantic governance that preserves its meaning.

This work assesses the readiness of cyber-physical and informational architecture. The objective is to identify dimensions, indicators, and methods used to evaluate hospital readiness in interoperability and digital integration. Also, the study aims to determine how CE/HTM is represented, and to propose a framework that articulates fragmented capabilities. The contribution is not another maturity model, nor a restatement of already known capabilities in medical technology management. It lies in treating CE/HTM as an explicit domain of assessment within an institutional readiness instrument, articulated with IT, interoperability, governance, and clinical workflow.

Frameworks such as IEC 80001-1 [23], digital maturity models, and HTM benchmarks are robust within their own fields, yet none assess hospital readiness by bringing these capabilities together.

2. Background and conceptual framework

2.1. Digital maturity and organizational readiness

Digital maturity models range from stages of EHR adoption to multidimensional assessments that incorporate governance, workforce, interoperability, and analytics [2], [4]–[10]. Organizational and implementation readiness frameworks approach the same problem from a different perspective, emphasizing leadership, culture, resources, competencies, and user participation [15, 24, 25, 26, 27, 28]. This literature shows that having technology does not equate to having an institutionalized capacity.

2.2. Interoperability, information, and cyber-physical integration

Hospital interoperability involves technical, syntactic, semantic, and organizational capabilities. Models such as the European Interoperability Maturity Model (IMM) and the EHR Interoperability Maturity Model (EHR-IMM) indicate that effective information exchange requires functional interfaces as well as governance mechanisms, standards, incentives, and supporting infrastructure [12, 13]. Studies on picture archiving and communication systems (PACS), open EHR, and secondary data extend this perspective by emphasizing semantics, quality, stewardship, and data reuse [21], [29]–[30]. For this reason, this work maintains interoperability (D5) and information management (D6) as distinct domains.

The expansion of IoMT (Internet of Medical Things) introduces an additional cyber-physical layer. Studies on medical equipment, smart hospitals, and medical IT networks describe barriers related to legacy systems, interoperability, cybersecurity, lifecycle management, and shared responsibilities [17]–[21, 23, 31]. IEC 80001-1 is particularly relevant because it formalizes risk management, defined roles, and lifecycle processes when medical devices connect to IT networks [23]. What remains unresolved is how these specialized capabilities connect to the institutional dimensions of readiness.

3. Methodology

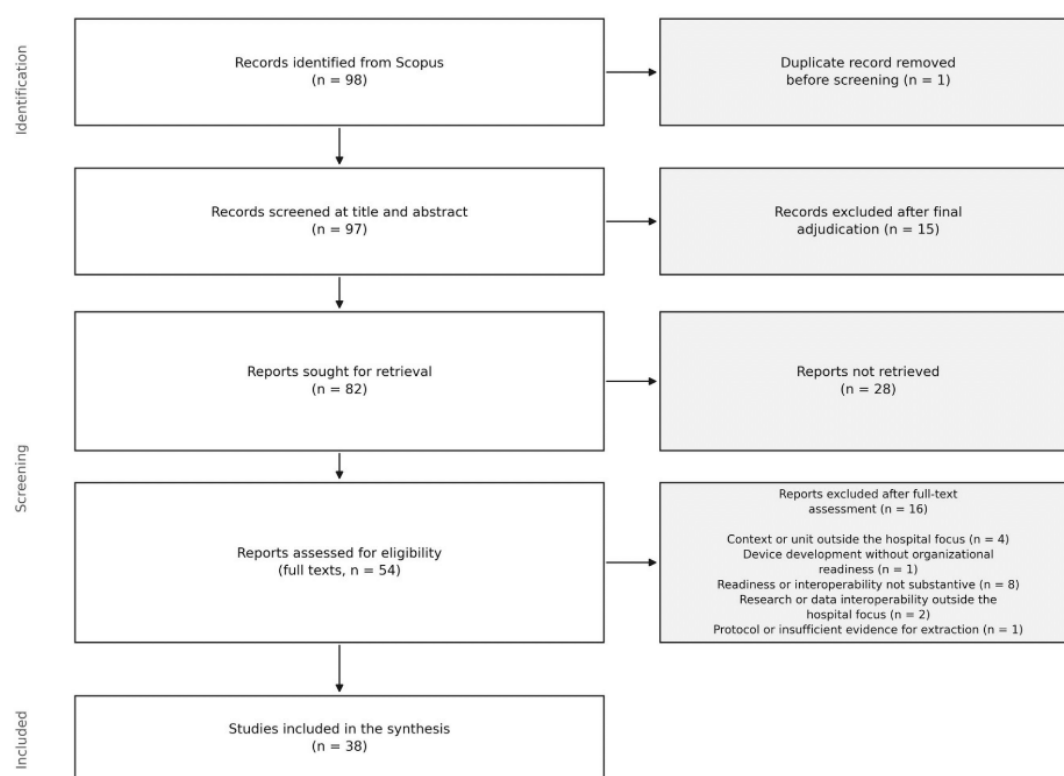
3.1. Design and search

A Scopus-based rapid scoping review was performed and reported following the PRISMA-ScR framework [32]. The full search string and study selection process are reported in Supplementary Material S1. This review addresses the dimensions, indicators, and evaluation methods that have been used to

assess hospital readiness for medical device interoperability and CE-IT integration with HIS/EHR. This investigation also seeks to answer what gaps stand in the way of an integrated framework.

The final search strategy (version 4) combined hospital/healthcare organization terms with readiness, maturity, interoperability, and integration, together with a specific block on medical devices, medical IT networks, and CE/HTM. No temporal or document-type filters were applied. The search/export was conducted on August 17, 2026. The restriction to a single database is a deliberate choice in this rapid review, and this is discussed later as a limitation.

The search identified 98 records, of which one duplicate was removed. 97 records were screened against the pre-specified population, concept, and context criteria. The initial screening register marked 65 records for full-text assessment, and 32 were excluded. A traceability audit of the retrieved files showed that 17 of those 32 records had been assessed in full text, so these cases were formally re-adjudicated against the final eligibility criteria. In this case, seven studies met the inclusion criteria and ten were excluded after full-text assessment. Therefore, fifteen records remained excluded at screening, and 82 reports were sought for retrieval. Also, 28 reports could not be obtained because of technical access barriers and platform-related restrictions, and 54 valid full texts were assessed for eligibility. Of these studies, 16 were excluded, and 38 formed the final corpus. For the studies to be included, it was required that readiness/maturity, interoperability/information integration, or device integration and CE/HTM be a substantive focus of the study (objective, method, or outcomes). The review is classified as a rapid review because it was restricted to Scopus, and the full-text retrieval was 65.9% of the reports sought. Figure 1 summarizes the selection process from identification to inclusion, following the PRISMA-ScR flow.



Rapid scoping review based on Scopus

Note. Seventeen records initially marked as excluded at title and abstract were re-adjudicated because a full text had already been retrieved and assessed; seven met the inclusion criteria and ten were excluded after full-text assessment. Full-text retrieval reached 65.9% of the 82 reports sought. The route of every record is documented in Supplementary Material S1.

Figure 1: Study selection flow.

3.2. Extraction, crosswalk, and synthesis

For each study, the extracted data included design (unit, object, method), assessment characteristics (framework/model/instrument, domains, indicators, scale, standards/architectures), and the contextual factors (barriers, facilitators, stakeholders, and potential contribution). An explicit distinction was made between the assessment framework and the research method; interviews, regression, PRISMA, partial least squares structural equation modelling (PLS-SEM) or process mining [33] were not automatically treated as maturity frameworks.

Extraction and coding were performed by the first author and subsequently reviewed by the second author. The extraction and the crosswalk were then audited for internal consistency and traceability. No duplicate independent coding was carried out, and no formal inter-rater reliability statistics were computed.

The complete traceability of the analysis is preserved in the **Analysis Matrix – Supplementary Material S1**, which presents a row for each of the 38 studies and integrates bibliographic identification, methodological characterization, framework, assessment method, scale, barriers, facilitators, stakeholders and the coding used in the synthesis. Each study included is identified by its DOI and Scopus EID, so that the corpus can be retrieved as assessed. Each row is accompanied by a written justification of the evidence on which the coding was based; this allows any individual assignment to be traced back to the primary study. This matrix constitutes the source of verification of the aggregate results reported in the body of the article.

The synthesis used ten domains: D1 Strategy & Leadership; D2 Governance & Organization; D3 Clinical Engineering & HTM; D4 IT Infrastructure & Architecture; D5 Interoperability & Standards; D6 Data & Information Management; D7 Cybersecurity, Privacy & Risk; D8 People, Competencies & Culture; D9 Clinical Workflow & Implementation; and D10 External Ecosystem & Sustainability. Each domain received one of three codes depending on the weight it carried within the study's assessment framework. A domain was coded as central or strong (2) when it constituted a structural dimension of that framework or an explicitly substantiated main criterion. When it appeared only in passing or as a supporting element, the code was partial or secondary (1), and when the study did not address it at all, the code was absent (0).

To illustrate the application of the scale, three examples of the D3 Clinical Engineering & HTM domain are reported, one for each code (Supplementary Material S1, Appendix B). D3 serves as the reference domain for co-occurrence analysis because it is the differential axis of the proposed framework. CE/HTM had been defined as a concept of interest before screening, since it formed part of the review question. D3 was selected after the descriptive coverage analysis as an exploratory reference domain. This post hoc choice is acknowledged, and the co-occurrence analysis is interpreted as descriptive rather than confirmatory.

The development of the framework followed four steps: typology of models; barrier/enabler and stakeholder analysis; grouping of domains into capacity components; and derivation of technologically neutral constructs and criteria.

Domains were assigned to components by applying three sequential rules. First, each domain was classified according to whether it described a capability under the hospital's direct control or an external condition, with the latter retained as an enveloping context and not scored. Second, among the remaining domains, those that applied across all layers and not to a specific one were designated transversal. The third rule grouped the remaining domains according to the function they perform in readiness, so that each component corresponds to a functional role and not to a technology or an organizational unit.

The preliminary scale harmonized five capacity states coded 0-4. A five-state structure was adopted because this type of structure predominates among the established maturity-model lineages identified in the corpus. This includes formulations derived from CMMI and ISO/IEC 15504, the stages of the Health Information Sharing Maturity Model (HISMM), the PACS maturity framework, and hoc-to-seamless progressions. Some models in the corpus use only three levels, others eight stages. Three levels do not separate institutionalization from routine management. And the eight-stage ladders presuppose a technology adoption path that a technology-neutral instrument should avoid.

4. Results

4.1. Assessment of Features and Families

The resulting corpus was methodologically heterogeneous, as Table 1 shows. Twenty of the 38 studies contributed empirical or instrument-development evidence. The remaining eighteen investigations were reviews or conceptual and normative papers. Thirteen studies applied formal readiness or maturity instruments, and ten studies mapped several existing frameworks. The assessment evidence in this field therefore extends beyond classic maturity models. The organizational scope ranged from single centers to multi-country studies, with national-level assessments the most frequent single category.

Table 1

Methodological characteristics of the included corpus ($n = 38$).

Block	Category	n
Study design	Quantitative	6
	Qualitative	3
	Mixed methods	7
	Instrument design or evaluation	4
	Review, conceptual or normative	18
Assessment approach	Formal readiness or maturity instrument	13
	Mapping of existing frameworks	10
	Other assessment approaches	15
Organizational scope	Single center	4
	Multi-hospital	8
	National	9
	Multi-country	4
	Not applicable (review or conceptual)	13

Direct comparators address distinct assessment domains: the Digital Health Indicator (DHI) and the Electronic Medical Record Adoption Model (EMRAM) for digital maturity; the Networkability Maturity Model (NMM) for networkability; the IMM and the EHR-IMM for exchange; the HISMM for information sharing; the process assessment and process reference models (PAM/PRM) of IEC 80001-1 for medical IT network risk; and the Five-Pillar Intelligence Readiness Framework as an integrative antecedent [5, 7, 10, 12, 13, 14, 22, 23, 34, 35]. Table 2 below contrasts each comparator with the proposed framework, identifying the specific coverage gap that motivates the present proposal.

4.2. Multi-domain coverage and fragmentation

D5 Interoperability & Standards presented strong evidence in 29/38 studies (76.3%), D4 IT Infrastructure & Architecture in 24/38 (63.2%) and D2 Governance & Organization in 23/38 (60.5%). D3 Clinical Engineering & HTM was coded as central (2) in fewer studies than any other domain: 7/38 studies (18.4%) coded it as central, 6/38 as partial, and 25/38 (65.8%) as absent. This result describes the centrality of the domain in the studies, not the actual presence of CE/HTM in hospitals.

Pairwise combinations with D3 ranged from 2/38 (D3+D2) to 5/38 (D3+D4 and D3+D7), and only one study simultaneously integrated D3+D4+D5+D2+D9. In contrast, the D2+D4+D5+D9 core without requiring D3 was more frequent. These counts rest on the seven studies that coded D3 as strong. This results in a denominator small enough to cap any combination involving that domain. Within those seven, D3 co-occurred with an average of 3.7 other strongly coded domains per study, a value inside the 3.4 to 4.4 range obtained when the same calculation is applied to each of the remaining domains.

Table 2

Direct comparators and gap with respect to the proposed framework.

Framework	Focus	Coverage	Gap relative to the proposed framework
DHI [5, 7, 10]	Digital maturity	Governance/workforce, interoperability, analytics	CE/HTM and device lifecycles are not explicit domains.
NMM [14]	Networkability	Alignment, architecture, process, cooperation	CE/HTM is not an explicit capability.
EHR-IMM [13]	EHR Interoperability	Governance, standards, incentives, infrastructure.	Focuses on EHRs.
EU IMM [12]	Service interoperability	Delivery, consumption, management	Does not incorporate CE-IT integration.
HISMM [34]	Information sharing	Technology, use and governance	Does not incorporate device lifecycle.
IEC 80001-1 PAM/PRM [23]	Medical IT network risk	Roles, risk interfaces, lifecycle	Does not assess complete hospital readiness.
Five-Pillar [22]	Smart Operations	Interoperability, workflow, support, security	Integrative, but without validated and replicated assessment.

The corpus therefore shows that CE/HTM is rarely treated as a central domain. Only one study, however, combined it with IT infrastructure, interoperability, governance, and clinical workflow at the same time. The complete pattern appears in Figure 2, where Panel A shows the 0-1-2 coverage of the ten domains across the corpus, and Panel B shows the strong co-occurrences of D3 with the domains most relevant to integration.

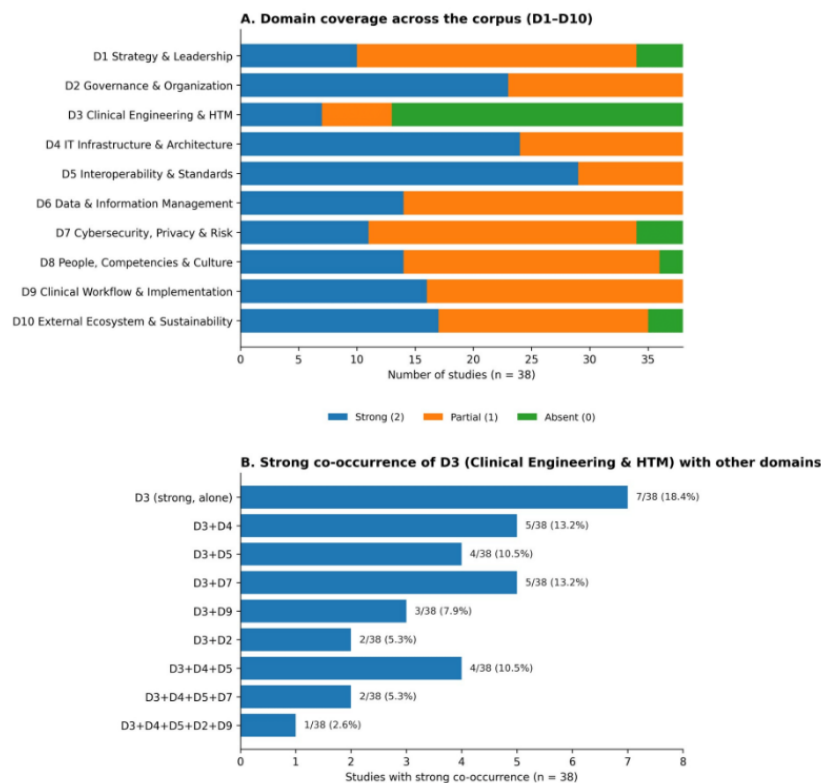


Figure 2: Domain coverage and fragmentation of CE/HTM. Panel A: 0-1-2 coverage of D1-D10. Panel B: Strong co-occurrences of D3 with critical domains.

4.3. Barriers, facilitators and stakeholders

Technical interoperability and interfaces were the most recurrent cross-cutting theme (27/38; 71.1%), followed by governance/leadership/coordination (21/38; 55.3%). Financial sustainability and resources, skills/training, network infrastructure/platforms, and regulatory environment/policies followed at closely clustered frequencies, ranging from 16/38 (42.1%) to 20/38 (52.6%). CE/HTM appeared as an explicit barrier in 8/38 studies (21.1%), typically concerning device connectivity or equipment lifecycle management.

Clinicians/medical leadership were explicit stakeholders in 32/38 studies, senior management/management in 31/38, and IT/Digital Health/Health Informatics in 24/38. CE/Biomedical Engineering/HTM appeared in 6/38 (15.8%) and explicit CE-IT co-representation was found in 3/38 [20, 21, 23]. The clearest case of shared responsibilities was the assessment based on IEC 80001-1 [23]. These figures are interpreted as representations in the literature and not as organizational prevalence.

5. Proposed integrated framework

5.1. Architecture

The proposal does not replace existing models; it articulates them. It is organized into four components: (1) institutional preparation, which integrates D1 and D2; (2) cyber-physical integration capability, D3 and D4; (3) interoperability and information capability, D5 and D6; and (4) clinical and operational integration, D9. D7 Cybersecurity, Privacy & Risk and D8 People, Competencies & Culture are transversal, while D10 External Ecosystem & Sustainability constitutes the enveloping context. The architecture describes related capabilities, not a causal sequence or a mandatory time path. Figure 3 represents this architecture, showing the four components, the two transversal domains, and the enveloping context.

The domains were assigned to components according to functional dependency and not temporal sequence. Institutional readiness establishes the organizational conditions under which CE/HTM and IT can be integrated. Cyber-physical integration provides the connectivity and architecture on which interoperability depends, and interoperability and information management determine whether the resulting exchange reaches clinical processes in a usable form. A hospital may hold strong capabilities in a later component while lacking earlier ones, and the framework is intended to show those imbalances.

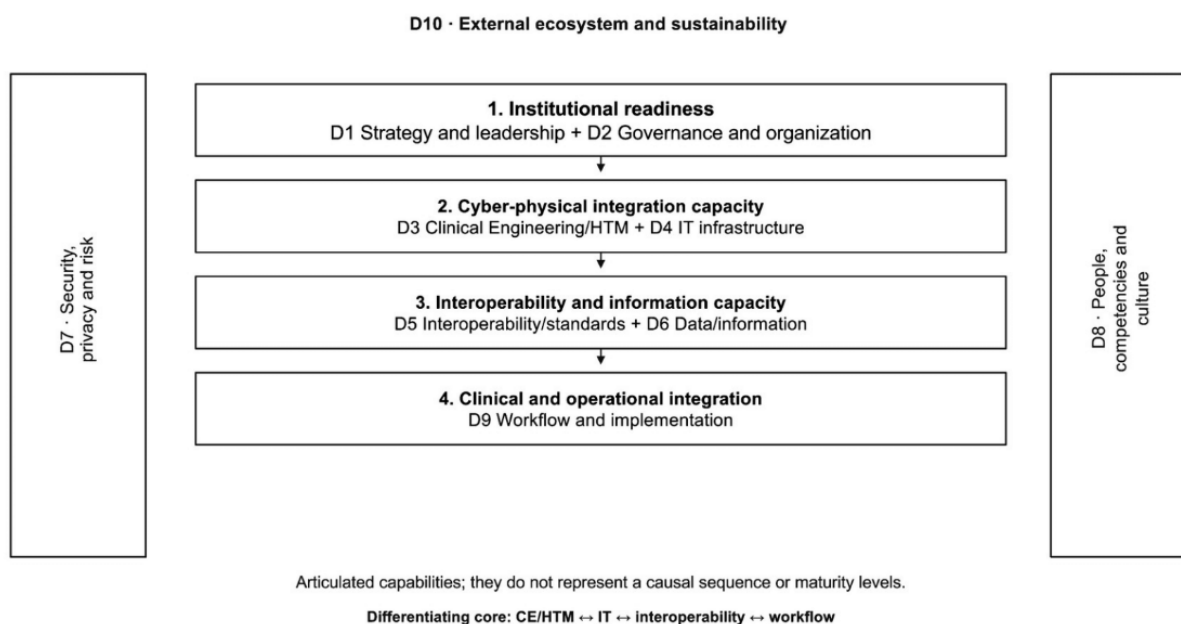


Figure 3: Integrated conceptual framework for hospital preparedness.

Table 3 specifies the domains, capabilities, and function of each component.

Table 3

Architecture, domains and capabilities of the proposed framework.

Component	Domains	Capabilities	Function
Institutional readiness	D1+D2	Strategy, resources, governance, change	Direction, authority, and coordination.
Cyber-physical integration	D3+D4	Devices/lifecycle management, HIS/EHR, networks	Connect physical medical technology with IT.
Interoperability and information	D5+D6	Interfaces, Semantics, Quality, Stewardship, Analytics	Interpretable and governed exchange.
Clinical-operational integration	D9	Workflow, usability, automation	Insert technology into real processes.
Transversal	D7	Risk, Cybersecurity, Privacy and access	Clinical and Information Security.
Transversal	D8	Competencies, training engagement	Adoption and learning.
Background	D10	Vendor and procurement; Regulation and external financing	Separates internal response from environment.

5.2. Preliminary operationalization

The synthesis derived 21 constructs distributed across the ten domains. Twenty of them are scorable and generate 21 scoring criteria. D3.1 is represented by two criteria because tracing the perimeter of connected devices and the demonstration of functional exchange are distinct capabilities that a single score would conflate. The twenty-first construct, D10.2, describes regulation, policies, financing, and external infrastructure. It is not scored because its determinants lie outside the hospital's direct control. Table 4 presents the full set of criteria with their domain, construct, and primary verifiable evidence.

Table 4

Preliminary operationalization: constructs, scoring criteria and required evidence.

Domain	Construct	What is assessed	Evidence
D1	Strategic alignment & leadership	Digital strategy aligned with institutional objectives, with executive sponsorship and prioritization of integration initiatives	Roadmap, minutes, decision portfolio
	Resource & investment readiness	Resource planning sufficient to implement, maintain and renew digital capabilities	Budget, investments, business case
D2	Multidisciplinary digital governance	Formal governance with functional representation, roles, authority and escalation routes	Structure, responsibility matrix, policies, minutes
	Change & implementation governance	Documented process for change, deployment, incidents and coordinated follow-up	Change plan, issue logs, follow-up records

D3	Device connectivity: traceability (1 of 2)	Traceability of which devices are connected and which exchange data	Maintenance management (CMMS) or asset management (EAM) inventory, network diagrams
	Device connectivity: exchange (2 of 2)	Demonstrable automated exchange and interface status where integration is pertinent	Interface logs, integration tests, gateways
	Digital HTM life-cycle capability	Lifecycle traceability used to plan and document equipment support	CMMS, commissioning and maintenance records
D4	HIS/EHR deployment & integration	Documented functional coverage and architecture enabling managed interfaces	Application catalogue, architecture, interfaces
	Network & platform readiness	Connectivity, capacity, performance, continuity and recovery monitored and managed	Network metrics, incidents, continuity plans
D5	Standards & interface capability	Interfaces use fit-for-purpose specifications with demonstrable exchange	Specifications, interface catalogue, test results
	Semantic interoperability	Governed semantic representations with maintain	Terminologies, vocabulary policies, mapping tables
D6	Data quality & stewardship	Rules, roles and processes for quality, availability, traceability and stewardship	Quality rules, data profiles, stewardship roles
	Integrated data & analytics readiness	Repositories and traceable processes for accessing and reusing authorized data	Repositories, data lineage, extraction procedures
D7	Medical IT network & device risk governance	Formal risk cycle with roles, change and interface assessment, and risk communication	Risk policy, commissioning and change records
	Cybersecurity & access controls	Risk-proportional controls with monitoring, review and response capabilities	Control configuration, logs, incident response
	Privacy & information access governance	Traceable rules for authorization, consent, privacy and auditing	Access policies, consents, audit logs, privacy impact assessment
D8	Digital competencies & training	Required competencies identified and structured training with evidence of coverage	Competency profiles, gap assessment, training records
	User engagement & change readiness	Traceable user participation in design, implementation and evaluation	Workshops, user acceptance testing, feedback logs, issue tracking
D9	Workflow integration & usability	Workflow fit assessed, with friction and usability monitored and acted upon	Process maps, observation, usage and alert metrics
	Automation of data handling	Capture, transfer or reuse automated where appropriate; manual re-entry identified	Interface records, workflow audit, transfer logs

D10	Vendor & procurement governance	Contracts with verifiable integration, security and portability requirements	Tender documents, contracts, service level reviews
	External regulatory & funding environment (contextual, not scored)	Regulation, incentives, funding and external infrastructure recorded as context	Regulation, policies, programmes, funding

The provisional scale uses five states, each defined by how far the capability is institutionalized. In Table 5, each state is defined.

Table 5

Capability states of the preliminary 0-4 scale.

Capability state	Generic definition
0 - Absent / ad hoc	The capability is not identifiable or exists only through undocumented individual practice.
1 - Initial / emerging	The capability exists in isolated projects, areas, or reactive responses, without consistent institutional management.
2 - Defined/standardized	The capability is documented and formally established for the pertinent scope, with assigned responsibilities.
3 - Integrated / managed	The capability operates routinely across relevant services and is monitored, reviewed, and coordinated with adjacent domains.
4 - Optimized / learning	The capability is continuously adjusted using metrics, incidents and organizational learning.

The anchors were formulated as demonstrable and technology-neutral capabilities. Standards and tools such as Fast Healthcare Interoperability Resources (FHIR), Digital Imaging and Communications in Medicine (DICOM) and open EHR, or infrastructure such as cloud services, computerized maintenance management systems (CMMS) and virtual local area networks (VLAN), together with IEC 80001-1, are cited by their established designations and function here as possible forms of evidence. No global weightings or cut-off points were defined.

6. Discussion

6.1. Institutional readiness and diagnostic data fidelity

The proposed framework does not model biological processes or perform diagnostic analysis; it delimits the architectural conditions on which both depend. This distinction is deliberate and places the contribution at the interface between clinical engineering infrastructure and the computational abstraction of clinical data.

The analysis that follows requires a distinction between three levels of claim. First, the coverage and co-occurrence pattern is a finding of the review itself. Second, the mechanisms linking fragmentation to data fidelity are conceptual interpretations grounded in external literature and standards and are not findings generated by this review. Third, their empirical verification remains a task for future research.

On this basis, the framework offers an analytical vocabulary for locating where degradation in the device-to-EHR chain may plausibly originate. Where cyber-physical integration (D3-D4) does not guarantee that the perimeter of connected devices is traceable and validated, the conditions for verifying data provenance are not in place. The same applies when interoperability (D5) transmits syntactically

correct messages that lack common semantics, or when data governance (D6) leaves quality, lineage, or stewardship unassured. Under such conditions, the fidelity of the inputs on which any downstream model operates cannot be verified institutionally [36], and the CE-IT risk coordination formalized by IEC 80001-1 [23] remains a formal requirement without operational expression. A readiness tool that makes explicit the lifecycle of the devices and the semantic traceability therefore supports a prior organizational diagnosis that complements the analytical treatment of data quality.

Accordingly, the framework does not compete with the analytical and modeling approaches that pursue minimal information loss. It characterizes institutional capabilities that plausibly condition the environment in which such approaches operate, and it enables interdisciplinary articulation between clinical engineering, IT, data science, and modeling. Whether higher scores bring measurable improvements in data fidelity lies beyond the scope of this review and remains an empirical question.

6.2. Conceptual contribution

The review found an asymmetry pattern between assessment families. Each family covers a distinct portion of the readiness space, and none covers CE/HTM alongside interoperability, governance, and clinical workflow. The proposed framework brings these separate capabilities into one structure and organizes their contribution without ranking the source models.

The D3 result should be interpreted with caution. It reflects how the reviewed literature frames Clinical Engineering, not how hospitals practice it. Some studies use different terminology, others are indexed under broader digital health categories, and several focus on domains outside Clinical Engineering [37].

The methodological finding is that CE/HTM is rarely assessed as an explicit domain. Making it visible allows connectivity, commissioning, lifecycle, interfaces, and CE-IT shared risk to be incorporated into the readiness inventory.

6.3. Why separate cyber-physical integration, interoperability, and data governance

A connected device is not necessarily interoperable, and interoperability does not automatically produce data quality. A device can be networked without exchanging useful information; an interface can function without the organization knowing its dependence on assets; and syntactically valid messages may lack common semantics, stewardship, or traceability. The separation between D3-D4 and D5-D6 allows the framework to locate these imbalances more precisely and avoids turning a specific technology into a synonym for maturity.

6.4. Governance and usefulness for hospital decisions

The CE-IT interface is a technical and organizational matter. IEC 80001-1 shows that connecting medical equipment creates a shared risk space that requires roles, validation, and communication [23]. The framework places this coordination in governance (D2) and risk (D7), while maintaining D3 visibility and device lifecycle. In this way, CE/HTM is not absorbed into IT or treated as a peripheral player.

Readiness should be used as a capability profile and not as a product inventory, since adoption levels vary across clinical and operational domains within the same institution [38]. A hospital with consolidated EHR but low D3 capacity may prioritize connectivity, lifecycle, and commissioning. Another with strong D3-D4 and weak D5-D6 can concentrate on interfaces, semantics, and stewardship. When the gap is in D2, D8, or D9, the answer requires governance, training, or workflow redesign. The same approach can guide procurement through verifiable requirements for interoperability, security, support, and portability [39].

6.5. Validation pending

The 21 criteria should not yet be added together as if they were metrically equivalent, since the unequal number of criteria per construct introduces accidental weighting. At this stage, the most defensible

result is a profile by constructs, domains, or components accompanied by evidence.

The next stage should include content validity with experts in CE/HTM, IT, interoperability/data, cybersecurity, quality/risk, clinical leadership, and management; piloting to measure feasibility and missing evidence; and inter-rater reliability on the ordinal scale. Only then would it be reasonable to study aggregation, cut-off points, sensitivity to change, or associations with operational indicators.

For the next steps, a small-scale pilot would be strategic. A feasible design could include two or three hospitals with contrasting profiles. For example, a single center with a consolidated EHR alongside a multi-hospital network with heterogeneous device infrastructure. Each institution would be assessed independently by a CE/HTM lead and an IT lead using the 21 criteria. This pilot would help determine if the required evidence is retrievable in routine practice, and how long an assessment takes. Its outputs would inform the wording of the anchors, the rules for non-applicability and insufficient evidence, and the feasibility of the instrument before any comparative use.

7. Limitations and future work

The search was restricted to Scopus, and more than a quarter of the reports sought could not be retrieved. Availability introduced a clear bias: 88.9% of the texts assessed were open access, against 3.6% of those not retrieved, which consisted mainly of conference papers and book chapters. For this reason, the corpus may overrepresent open-access literature, and the reported frequencies describe the retrieved corpus and not the wider body of evidence. The 0-1-2 crosswalk is an analytical synthesis and does not yet have formal inter-rater reliability. Co-occurrences describe the joint presence of domains, not causality or superiority of models. Finally, the criteria and anchors on the 0-4 scale constitute conceptual operationalization, not a validated instrument, and the framework should not be used as a comparative scale until formal validation has been completed.

Future work should expand the range of sources, validate content and clarity, test the instrument in hospitals, define rules for non-applicability or insufficient evidence, and assess agreement among evaluators. Global aggregation, if used, should be justified after these steps and avoid double counting of transversal domains.

8. Conclusion

Hospital readiness to integrate medical devices and HIS is distributed across models of digital maturity, interoperability, implementation readiness, data governance, and management of medical IT networks. Interoperability, infrastructure, and governance are widely represented, while CE/HTM was coded as central in fewer studies than any other domain. In those few studies, it appeared together with as many other domains as the rest did. The gap lies in how rarely CE/HTM is assessed as an explicit domain.

The proposed framework in this study articulates institutional preparedness, cyber-physical integration, interoperability/information, and clinical-operational integration, with security/risk and people/culture as cross-cutting dimensions. Its proposed differential contribution is to make explicit the lifecycle of devices and CE-IT coordination without prescribing specific technologies; this contribution remains to be tested. By making the device-to-EHR chain explicit, the framework supports the environments in which diagnostic modeling and advanced data analysis operate, rather than replacing them. Preliminary operationalization provides a basis for further validation but should not yet be used as a validated comparative scale.

Supplementary material

Supplementary Material S1 — Analysis and Traceability Matrix: The file contains: the V4 search protocol and strategy; a record-level reconciliation of the selection flow for all 98 records (S0b_PRISMA_Reconciliation); the characterization of the 38 included studies; the extraction of frameworks, methods and scales; the D1-D10 crosswalk and the per-domain co-occurrence calculation

(S2b_Cooccurrence_by_domain); the synthesis of barriers, facilitators and stakeholders; the conceptual architecture; the proposed criteria and 0-4 anchors; and three worked examples of D3 coding decisions (Appendix B).

The following bookmark will be replaced by the permalink to the repository: **[Material_Suplementario_S1_Matriz_Analisis.xlsx]**

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Declaration on Generative AI

During the preparation of this manuscript, the authors used generative AI and AI-assisted tools, including ChatGPT (OpenAI), Claude (Anthropic), Gemini Pro (Google), Microsoft Copilot, and Llama-based models (Meta), to improve grammar and linguistic precision of the manuscript. These tools were not used for data analysis, interpretation of results, generation of scientific findings, or methodological decision-making. All AI-assisted content was critically reviewed, verified, and edited by the authors to ensure accuracy, consistency, and scientific integrity. The authors take full responsibility for the final content of the publication.

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