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Structural alignment and thematic complementarity between ISO 7101:2023 and Türkiye's hospital quality standards: a qualitative document analysis

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Abstract

Background ISO 7101:2023, adopted in Türkiye as TS ISO 7101:2023, is an international management system standard for healthcare quality management published by the International Organization for Standardization (ISO) in October 2023 and structured according to ISO's harmonised high-level architecture. SKS Hastane Sürüm 6.1 (Sağlıkta Kalite Standartları Hastane Sürüm 6.1) is Türkiye's national hospital quality standards framework, comprising 5 dimensions, 46 sections, 523 standards, and 1,599 assessment criteria calibrated to hospital practice. Both documents coexisted within the Turkish health system at the time of this analysis: TS ISO 7101:2023 was adopted by the Turkish Standards Institution (TSE) in November 2023, while SKS Hastane Sürüm 6.1 has been in use since its publication in 2021. Despite the potential relevance of both frameworks to hospital quality governance, to the author's knowledge, no published study has systematically compared the structural and thematic alignment of ISO 7101:2023 and SKS Hastane Sürüm 6.1. This study aimed to examine the degree and nature of correspondence between ISO 7101:2023 and SKS Hastane Sürüm 6.1 across a comprehensive set of hospital quality management domains.

Methods A qualitative document analysis with structured comparative mapping was conducted using the primary texts of ISO 7101:2023 (accessed as TS ISO 7101:2023) and SKS Hastane Sürüm 6.1. Fourteen analytical dimensions were specified a priori, covering organisational context, leadership and governance, quality planning, patient/person-centred care, patient safety and risk management, workforce competence, clinical and service delivery processes, information management, resource and infrastructure management, external provider management, performance measurement, incident reporting and learning, continuous improvement, and accessibility and equity. A seven-category coding scheme was applied to each dimension: Full Convergence (FC), Partial Convergence (PC), ISO-Dominant Management System Emphasis (ISO-D), SKS-Dominant Operational Specificity (SKS-D), Complementarity (COMP), Limited Explicit Correspondence (LEC), and No Direct Correspondence (NDC). Coding categories are analytical, not evaluative. Standard-level verification extending to confirmed standard codes and assessment-criteria-level content was conducted for five dimensions (D2, D3, D5, D8, D11). ISO 7101:2023 text is paraphrased with clause references; the document is copyrighted and is not extensively quoted.

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Results Thirteen of the fourteen analytical dimensions were classified as Partial Convergence (PC). Dimension 7 (Clinical and Service Delivery Processes) was classified as Complementarity (COMP). No dimension was classified as Full Convergence or No Direct Correspondence. The Partial Convergence pattern reflects shared quality management intent across all domains, accompanied by systematic differences in documentary logic, prescriptive specificity, and regulatory mechanism. ISO 7101:2023 addresses quality domains through normative "shall" obligations within a harmonised management system architecture, leaving implementation methods to the organisation. SKS Hastane Sürüm 6.1 addresses the same domains through prescriptive, surveyable hospital standards and assessment criteria. Standard-level verification confirmed operationally specific requirements in SKS across governance committee structures (KKY06-10), risk management (KRY01-05), patient safety (KKY07), information system security and backup (DBY05, DBY10, DBY13), indicator management (GGİ01–07), and national performance reporting. Several ISO constructs — including formal change management planning (Cl. 6.3), risk awareness culture monitoring (Cl. 6.1.2), structured internal audit with independence criteria (Cl. 9.2), and eleven-input management review (Cl. 9.3) — were not confirmed as single equivalent standards in the verified SKS sections.

Conclusions ISO 7101:2023 and SKS Hastane Sürüm 6.1 show broad thematic overlap across hospital quality domains. SKS Hastane Sürüm 6.1 provides an operationally specific, nationally calibrated quality infrastructure for hospitals in Türkiye. ISO 7101:2023 provides a complementary management-system architecture that may supplement SKS's operational standards with structural constructs for leadership accountability, quality objective documentation, change management planning, and cyclical system evaluation. The two frameworks are better characterised as potentially complementary than as competing. These findings are based on document-level analysis and cannot be interpreted as evidence of implementation effectiveness. Empirical research is needed to assess how the frameworks interact in hospital practice and to determine what benefits, if any, alignment may offer for hospital quality governance in Türkiye.

Keywords ISO 7101:2023, Healthcare quality management, Hospital quality standards, SKS Hastane, Sağlıkta Kalite Standartları, Patient safety, Health services management, Document analysis

Background

Healthcare quality management has become a central preoccupation of health systems governance internationally. The recognition that health services must be not only safe and effective but also timely, efficient, equitable, and person-centred has driven the proliferation of quality frameworks, standards, and assessment systems across countries at all income levels [1, 2]. Hospitals, as the most structurally complex and resource-intensive institutions within health systems, have been primary targets of these quality improvement efforts, and a diverse international landscape of hospital quality standards, assessment programmes, and management system frameworks has developed over recent decades [3–5].

Within this landscape, management system standards developed by the International Organization for Standardization (ISO) have occupied an increasingly prominent position. ISO management system standards, characterised by their harmonised high-level structure, normative requirements expressed as "shall" obligations, and sector-agnostic applicability, have been widely adopted across industries for their capacity to provide organisations with a coherent governance architecture for quality, risk, and continual improvement [6]. In October 2023, ISO published ISO 7101:2023 Healthcare organization management: Management systems for quality in healthcare organizations: Requirements as the first edition of an international standard specifically designed for management systems for quality in healthcare organisations. Prepared by ISO Technical Committee TC 304, the standard establishes normative requirements applicable to any organisation providing healthcare services, regardless of type, size, or service provision, and is underpinned by the Plan-Do-Study-Act (PDSA) model of quality improvement. ISO 7101:2023 was adopted by the Turkish Standards Institution (TSE) as TS ISO 7101:2023 at its Technical Board meeting of 8 November 2023, formally entering the Turkish national standards landscape.

Türkiye's national hospital quality governance system is structured around the Sağlıkta Kalite Standartları (SKS) — Healthcare Quality Standards programme, established in 2003 as part of the Sağlıkta Dönüşüm Programı (Health Transformation Programme) and iteratively revised since then. The hospital-specific component, SKS Hastane, was most recently published as Sürüm 6.1 (Version 6.1) in August 2021 by the General Directorate of Health Services, Directorate of Healthcare Quality, Accreditation and Employee Rights [7]. SKS Hastane Sürüm 6.1 is designed for public, private, and university hospitals providing healthcare services in Türkiye and comprises 5 dimensions, 46 sections, 523 standards, and 1,599 assessment criteria. The framework is described as structurally, process-based, and outcome-oriented, with stated quality goals encompassing patient safety,

patient-centredness, effectiveness, efficiency, timeliness, continuity, equity, and healthy working life [8].

The concurrent presence of both ISO 7101:2023 and SKS Hastane Sürüm 6.1 within the Turkish health system creates a quality governance context in which hospital administrators, quality professionals, and national quality authorities may seek to understand how the two frameworks relate to one another. Such understanding is of practical significance: if the frameworks are substantively aligned, existing SKS compliance activities may simultaneously serve the quality management functions articulated in ISO 7101:2023; if they diverge, the nature and location of those divergences may inform decisions about quality system development, professional training, and policy. However, despite the publication of ISO 7101:2023 representing an important development in international healthcare quality management, to the author's knowledge, no published study has systematically compared the structural and thematic alignment of ISO 7101:2023 and Türkiye's national hospital quality standards.

To contextualise the novelty claim, a targeted contextual literature search was conducted prior to finalising this manuscript. The databases PubMed, Scopus, and Google Scholar were searched using the following terms and their combinations: 'ISO 7101', 'ISO 7101:2023', 'SKS Hastane', 'Sağlıkta Kalite Standartları', 'hospital quality standards Türkiye', and 'healthcare quality management system standard'. Grey literature sources, including the websites of the Turkish Standards Institution, the Turkish Ministry of Health, and ISO itself, were also consulted. No published study was identified that provides a systematic or structured comparative mapping of ISO 7101:2023 and SKS Hastane Sürüm 6.1. Relevant prior literature on healthcare quality standards comparison, ISO management system standards in healthcare, and Turkish hospital quality governance was identified and informs the Background section [7]. This search was targeted and contextual in scope rather than a formal systematic review, and the absence of identified comparable publications does not exclude the possibility that relevant unpublished or inaccessible analyses exist.

This study addresses that gap through a qualitative document analysis with structured comparative mapping. Using a pre-specified fourteen-dimension analytical framework and a seven-category coding scheme, the study compares the content of ISO 7101:2023 and SKS Hastane Sürüm 6.1 across the full range of hospital quality management domains addressed by both documents. The analysis is designed as non-hierarchical and non-evaluative: neither framework is treated as the reference point against which the other is measured, and all coding categories describe the documentary relationship between the two frameworks rather than the relative quality, completeness, or rigour of either.

The study addresses the following research questions: (1) How do the structural architectures and organisational design logic of ISO 7101:2023 and SKS Hastane Sürüm 6.1 compare in terms of their scope, hierarchy of requirements, and underlying quality management frameworks? (2) To what extent do the core quality management domains of ISO 7101:2023 correspond to equivalent or analogous requirements within SKS Hastane Sürüm 6.1? (3) What thematic areas or quality requirements are present in one framework but absent, less explicitly articulated, or addressed through substantially different mechanisms in the other? (4) What are the potential implications of the identified alignments and divergences for hospital quality governance and health services management in Türkiye?

Methods

Study design

This study employs qualitative document analysis with structured comparative mapping as its primary research method. Qualitative document analysis is a systematic procedure for reviewing, evaluating, and interpreting official or institutional documents, producing an analytically grounded account through processes of coding, thematic categorisation, and structured comparison [9, 10]. The approach is appropriate when the primary objective is to examine the content, architecture, and internal logic of documentary texts rather than to investigate human behaviour, clinical processes, or institutional performance. The comparative mapping component structures the analysis so that content from both primary documents is examined against a pre-specified set of analytical dimensions and assigned to operational coding categories, enabling a systematic, auditable, and reproducible comparison of two frameworks that differ in genre, origin, and national context. The study does not evaluate real-world implementation of either framework and makes no claims about hospital-level compliance, quality outcomes, or patient safety performance.

Document selection

Two officially published documents were selected as primary sources:

Document 1. TS ISO 7101:2023 — the Turkish Standards Institution (TSE) adoption of ISO 7101:2023 Healthcare organization management: Management systems for quality in healthcare organizations: Requirements, published in November 2023 following adoption at the TSE Technical Board meeting of 8 November 2023. The underlying international standard (ISO 7101:2023) was published by ISO in October 2023 and prepared by

ISO Technical Committee TC 304. This is the first edition of this standard.

Document 2. Sağlıkta Kalite Standartları Hastane Sürüm 6.1 (SKS Hastane Sürüm 6.1) — published by the General Directorate of Health Services, Directorate of Healthcare Quality, Accreditation and Employee Rights (Sağlıkta Kalite, Akreditasyon ve Çalışan Hakları Dairesi Başkanlığı), Republic of Türkiye. Version 6.1 was published in August 2021 as a minor revision of Version 6.0 (June 2020). The overall SKS programme has been developed iteratively since 2003.

ISO 7101:2023 is a copyrighted international standard; the version analysed in this study is TS ISO 7101:2023, accessed through the Turkish Standards Institution as an authorised national standards body. SKS Hastane Sürüm 6.1 is an officially published document of the Türkiye Ministry of Health, accessed through official channels. ISO 7101:2023 content is paraphrased throughout this study with clause references; extensive quotation is avoided in accordance with copyright requirements.

Document selection and scope boundaries

Only documentation applicable to the quality of hospital level healthcare services, published in the latest version at the time of analysis, and amenable to textual analysis was considered. There were two primary documents identified: ISO 7101:2023 / TS ISO 7101:2023 hospital management system and SKS hospital management system version 6.1. Since the analysis compares two documents and not a sample of the entire bibliographic literature, the boundaries below refer to the analysis and not to the inclusion/exclusion for a systematic review.

Scope exclusions were: implementation guides, audit reports, inspection reports, commentary, and secondary interpretations of either primary standard; previous versions of either primary document; other SKS sub-sets (SKS Tıp Merkezi, SKS Ağız ve Diş Sağlığı Hastanesi, SKS Diyaliz, SKS 112), since their structure is specific to their facility-type and is not hospital-level as both primary documents are; other quality frameworks for hospitals in health service provision (ISO 9001:2015, Joint Commission International (JCI) standards, EFQM). While not likely to be eligible for a systematic review, these exclusions are relevant to the present analysis [11].

Unit of analysis

The primary units of analysis differ between the two documents, reflecting their different structural architectures. For ISO 7101:2023, the primary unit is the individual clause or sub-clause within the normative body of the standard (Clauses 4–10); Clauses 1–3 are treated as contextual and definitional. For SKS Hastane Sürüm 6.1, the primary unit is the individual standard (standart) and its associated assessment criteria (değerlendirme ölçütleri), situated within their respective section (bölüm) and dimension (boyut). For the comparative mapping, the unit of comparison is the analytical dimension, given the substantial differences in structural granularity between the two documents that preclude reliable clause-to-standard equivalence for all domains.

Analytical framework

The comparison is structured using fourteen pre-specified analytical dimensions (Table 2) derived from review of the clause structure of ISO 7101:2023 (Clauses 1–10) and the dimension and section structure of SKS Hastane Sürüm 6.1 (5 dimensions, 46 sections), aligned with established domains in health services management and quality research. The analytical framework does not assume equivalence in scope, genre, or design philosophy between the two documents: ISO 7101:2023 is a management system standard using normative "shall" requirements within ISO's harmonised structure, underpinned by the Plan-Do-Study-Act (PDSA) model; SKS Hastane Sürüm 6.1 is a national hospital quality standards framework using prescriptive standards and assessment criteria with a scoring methodology, described in the document as structurally, process-based, and outcome-oriented. Neither framework is treated as the reference standard against which the other is measured.

Rationale for the analytical framework

The fourteen dimensions were not preconceived categories that the two documents were mapped to, but were identified through triangulation with a three-part reference model: the clause architecture of ISO 7101:2023 and its normative body (Clauses 4 through 10). These outlined the management system by order of context of the organization, leadership, planning, support, operation, performance evaluation and improvement. The second source was the SKS Hastane Sürüm 6.1 framework of five dimensions and forty-six sections covering governance, patient safety, person-centered care, workforce competence, information management, resource management, external provider management, performance measurement, incident learning and continual improvement within the institutional, clinical and support-service domains of hospital practice. The third source was the domains in the healthcare services quality management literature that were commonly reported irrespective of either framework, i.e. governance and leadership, patient safety, person-centered care, workforce competence, information management, resource management and external provider management [12, 13].

Such triangulation is necessary, because the two source documents are based on structurally incompatible logics. ISO 7101:2023 has its requirements organized in a clause/sub-clause structure in a harmonized

management system document architecture. SKS Hastane Sürüm 6.1's requirements appear in a hierarchy of dimension, section, standard and assessment criteria with a direct survey orientation to the hospital. No architectural mapping is possible between the two without an intermediate document-independent analytical level. The fourteen dimensions were constructed to serve that function: each dimension was defined to be broad enough that a node at any level within the two documents' respective hierarchies (clause-level in ISO; section-, standard- or criteria-level in SKS) would be covered, but sufficiently narrow that a single, traceable coding decision could be made for each document per dimension.

Finally, as is common in document analysis and in the structure-process-outcome model of reasoning in health services quality assessment literature [12], the 14 dimensions were validated against the quality of care constructs commonly found at the level of structure, process and outcome. Thus, the governance, staffing and physical dimensions suggest a structure focus, the clinical and service, information and incident and management dimensions suggest a process focus, while the performance measurement, continual improvement and access/equity dimensions suggest an outcomes focus, although the assessment does not consider measurement at the level of outcomes. The purpose of this procedure was to ensure the fourteen dimensions were both complete and conceptually distinct, rather than to categorize the content of documents under the structure-process-outcome typology. The fourteen-dimension analytical framework, and operational definition of each dimension, were fixed prior to systematic content extraction (see Comparative mapping process, Phase 2) and not changed following the commencement of coding.

Coding strategy

Coding was applied deductively using seven pre-specified coding categories (Table 3). The categories describe the nature of the relationship between the two documents' treatment of each analytical dimension and are not evaluative: no category implies that one framework is superior, more complete, or more rigorously developed than the other. Differences in emphasis are interpreted as reflecting differences in genre, scope, national context, and design purpose. For each analytical dimension, relevant content was extracted from ISO 7101:2023 (at the clause level) and from SKS Hastane Sürüm 6.1 (at the section and standard level), recorded with clause and section references, compared, and the most appropriate coding category assigned with documented rationale.

Comparative mapping process

The comparative mapping proceeded in six sequential phases: (1) orientation and familiarisation — full reading of both documents with initial annotation; (2) framework validation and adjustment — review of the fourteen analytical dimensions against actual document content, with the final analytical framework fixed before systematic extraction; (3) systematic content extraction — clause-by-clause extraction from ISO 7101:2023 (Cl. 4.1–10.2.2) and section-by-section extraction from SKS Hastane Sürüm 6.1 across all 5 dimensions and 46 sections; (4) coding — assignment of the coding category with documented rationale; (5) verification of claims — all factual claims verified against source documents, with unverified claims explicitly marked; and (6) synthesis and reporting.

Standard-level verification extending to confirmed standard codes and assessment-criteria-level content was conducted for five dimensions identified as requiring higher evidentiary depth: D2 (Leadership, Governance, and Accountability), D3 (Quality Planning and Strategic Objectives), D5 (Patient Safety and Risk Management), D8 (Information Management, Documentation, and Health Information Systems), and D11 (Measurement, Indicators, Monitoring, and Performance Evaluation).

Trustworthiness and methodological rigour

Trustworthiness was addressed using criteria adapted from established qualitative research methodology [9, 14]. Credibility was supported through detailed documentation of the analytical framework and coding procedures, transparent citation of clause and section references for all analytical claims, and explicit marking of unverified claims. Transferability is supported through rich description of both frameworks (Table 1), full specification of all analytical dimensions (Table 2), and operational definitions of all coding categories (Table 3). Dependability is supported through pre-specification of the analytical framework before coding, maintenance of a coded decision log, and use of fixed, operationally defined coding categories with explicit decision rules. Confirmability is supported through an audit trail of all analytical decisions, explicit reporting of partially unresolved items (see Summary of unresolved and partially unresolved areas in Results), and the non-suppression of divergence findings.

This study was conducted by a single author, consistent with established practice in exploratory qualitative document analysis, where a single-researcher design is appropriate provided that analytical transparency, reflexivity, and systematic documentation are maintained [9, 10]. To address the absence of independent inter-rater coding, the following procedures were implemented: (a) coding decision rules were specified in full prior to commencement of the final coding phase (Table 3); (b) a structured reflexive self-audit was conducted at a minimum two-week interval after initial coding, in which all fourteen dimensions were re-coded independently using

Table 1 Characteristics of the included documents

Characteristic	ISO 7101:2023 / TS ISO 7101:2023	SKS Hastane Sürüm 6.1
Full title	Healthcare organization management — Management systems for quality in healthcare organizations — Requirements	Sağlıkta Kalite Standartları Hastane Sürüm 6.1
Issuing body	International Organization for Standardization (ISO); adopted by Turkish Standards Institution (TSE) as TS ISO 7101:2023	General Directorate of Health Services, Directorate of Healthcare Quality, Accreditation and Employee Rights, Republic of Türkiye Ministry of Health
Publication date	ISO: October 2023; TSE adoption: November 2023	August 2021 (minor revision of Version 6.0, June 2020)
Edition / version	First edition	Version 6.1
Document type	International management system standard (normative)	National hospital quality standards framework (prescriptive)
Structural scope	10 clauses (Cl. 1–10); normative requirements in Cl. 4–10; harmonised high-level structure	5 dimensions; 46 sections; 523 standards; 1,599 assessment criteria
Stated applicability	Any organisation providing healthcare services, regardless of type, size, or services provided (Cl. 1, verified)	All public, private, and university hospitals providing healthcare services in Türkiye (verified from document text)
Quality model	Plan-Do-Study-Act (PDSA) (Introduction § 0.4, verified)	Structural, process-based, and outcome-oriented (yapısal, süreç bazlı ve sonuç odaklı, verified from document text)
Language	English (ISO original); Turkish (TSE adoption)	Turkish
Access	Copyrighted; accessible through authorised national standards bodies	Official publication of Türkiye Ministry of Health; accessed through official channels
Primary orientation	Management system architecture: governance, planning, operational control, performance evaluation, and improvement at the organisational level	Operational hospital quality infrastructure: prescriptive, surveyable standards and assessment criteria calibrated to hospital service delivery in Türkiye
Relevance to hospital quality governance in Türkiye	Provides a recognised international QMS framework applicable to any healthcare organisation; adopted by TSE as TS ISO 7101:2023; potentially applicable to Turkish hospitals as a supplementary governance architecture	The primary regulatory quality standards framework for hospitals in Türkiye; forms the basis for hospital quality assessments conducted by the Ministry of Health; applicable to all hospital types in Türkiye

All entries are directly supported by text in the cited document (verified) or represent contextual information from the document (see text). YBÜ = Yoğun Bakım Ünitesi; YBKÜ = Yenidoğan Yoğun Bakım Ünitesi

the pre-specified decision rules; (c) a coded decision log was maintained, recording the rationale for each coding decision and for any revision made during the self-audit; (d) all items that remained unresolved or partially unresolved after the self-audit were documented and reported transparently in the Results section rather than suppressed or assigned a provisional code without disclosure; and (e) the full analytical basis for each coding decision is provided in Supplementary Table 1, enabling readers to inspect, evaluate, and challenge the analytical reasoning. Although this procedure cannot substitute for independent inter-rater coding, it was used to improve consistency, transparency, and confirmability in a single-author document analysis.

Ethical considerations

This study is a document analysis that does not involve human participants, personal or clinical data, or any intervention. Ethical review for human subjects research is not applicable. Both primary documents were accessed through authorised official channels. The study complies with copyright requirements: ISO 7101:2023 content is paraphrased with clause references and is not extensively quoted.

Methodological limitations

This study is subject to several a priori limitations, which are addressed in the Limitations section of the Discussion. Key limitations include: the document-level scope of the analysis, which cannot account for implementation in practice; the genre difference between a management system standard and a prescriptive national standards framework, which requires analytical judgment in establishing equivalence; the primary language of SKS Hastane Sürüm 6.1 being Turkish, which introduces translation considerations; a priori dimension specification, which may not accommodate all content areas equally; incomplete assessment-criteria-level coding for nine of the fourteen dimensions; temporal limitation in that both documents are subject to revision; and the single-author design, for which a structured reflexive self-audit was substituted for independent inter-rater coding.

Results

Overview of the comparative mapping

Fourteen analytical dimensions were compared across ISO 7101:2023 and SKS Hastane Sürüm 6.1 using qualitative document analysis and a seven-category coding scheme. Of the fourteen dimensions, thirteen were classified as Partial Convergence (PC) and one — Dimension 7 (Clinical and Service Delivery Processes) — as Complementarity (COMP). No dimension was classified as Full Convergence (FC) or No Direct Correspondence (NDC). This distribution indicates that the two frameworks address a common set of quality management domains while employing substantively different approaches to

Table 2 Analytical dimensions and operational definitions

Dim.	Dimension name	Operational definition (summary)	ISO 7101:2023 primary references	SKS Hastane Sürüm 6.1 primary references
D1	**Organisational Context and Scope**	Identification of internal/external context; QMS scope definition; stakeholder identification; mission, purpose, and values.	Cl. 4.1–4.4	Kurumsal Yapı (KKU01-02)
D2	**Leadership**, **Governance**, **and Accountability**	Top management commitment; governance structures; quality policy; accountability and roles.	Cl. 5.1–5.4	Kalite Yönetimi (KKY01-10); Kurumsal Yapı (KKU04-06)
D3	**Quality Planning and Strategic Objectives**	Risk and opportunity identification; measurable quality objectives; change management planning.	Cl. 6.1–6.3	Kalite Yönetimi (KKY04,KKY05,KKY12); Kurumsal Yapı (KKU02-03); Kurumsal Verimlilik (KKV02-03)
D4	**Patient/Person-Centred Care and Patient Experience**	Service user focus; experience assessment; health literacy; co-production; cultural inclusivity; patient rights and dignity.	Cl. 5.4; Cl. 8.10; Cl. 8.9(b)	Hasta Deneyimi; Yaşam Sonu Hizmetleri; Hasta Odaklılık
D5	**Patient Safety and Risk Management**	Patient safety framework; risk management; medication safety; surgical safety; infection prevention; fall prevention; diagnostic safety; safety culture.	Cl. 6.1.1–6.1.3; Cl. 8.12.1–8.12.9	Risk Yönetimi (KRY01-05); İstenmeyen Olay Bildirim Sistemi; KKY07 (13 patient safety domains)
D6	**Workforce Competence**, **Training**, **and Healthy Working Life**	Competence determination; credentialing; training; awareness; occupational health; workforce wellbeing.	Cl. 7.2–7.3; Cl. 8.10.7	Eğitim Yönetimi; Çalışan Sağlığı ve Güvenliği; Sağlıklı Çalışma Yaşamı; KKY08-09
D7	**Clinical and Service Delivery Processes**	Clinical process planning; service design; admission and discharge; informed consent; referral; care transfer; ethics; specialist clinical service areas.	Cl. 8.1; Cl. 8.7; Cl. 8.9; Cl. 8.11	Hasta Bakımı; Acil Servis; Ameliyathane; YBÜ; YBKÜ; Doğum; Laboratuvarlar; Kemoterapi; Palyatif Bakım (and further Sağlık Hizmetleri sections)
D8	**Information Management**, **Documentation**, **and Health Information Systems**	Documented information; health records; information system governance; cybersecurity; records audit; clinical communication.	Cl. 7.4.3; Cl. 7.5.1–7.5.6	Doküman Yönetimi (KDY01-02); Bilgi Yönetim Sistemi (DBY01-17); Tıbbi Kayıt ve Arşiv Hizmetleri (DTA03-07)
D9	**Resource**, **Infrastructure**, **Facility**, **Device**, **and Material Management**	Physical resources; facility management; medical equipment; materials; emergency preparedness; hospitality services.	Cl. 7.1; Cl. 8.2; Cl. 8.4–8.6	Tesis Yönetimi; Malzeme ve Cihaz Yönetimi; Otelcilik Hizmetleri; Afet ve Acil Durum Yönetimi; KBRN Yönetimi
D10	**External Providers and Outsourced Services**	Selection, monitoring, and accountability of external service providers.	Cl. 8.8	Dış Kaynak Kullanımı
D11	**Measurement**, **Indicators**, **Monitoring**, **and Performance Evaluation**	Quality indicators; monitoring and measurement; internal audit; management review; national reporting.	Cl. 9.1–9.3	Göstergelerin İzlenmesi (GGİ01–07); Kalite Yönetimi (KKY04-05)
D12	**Incident Reporting**, **Learning Systems**, **and Corrective and Preventive Action**	Adverse event reporting; root cause analysis; corrective and preventive action; learning from incidents.	Cl. 10.2	İstenmeyen Olay Bildirim Sistemi; Kalite Yönetimi (KKY12)
D13	**Continuous Improvement and Quality Culture**	Continual improvement; risk culture; quality culture; waste reduction; improvement integration.	Cl. 5.1(d); Cl. 6.1.2; Cl. 10.1; Cl. 10.3	Kalite Yönetimi; Kurumsal Verimlilik; Sosyal Sorumluluk
D14	**Accessibility**, **Equity**, **and Universal Health Coverage**	Equitable access; affordability; inclusivity; universal health coverage; financial protection.	Cl. 5.5; Cl. 8.10.4	Hizmete Erişim; Hakkaniyet (stated quality goal)

All SKS section references are verified from Table 2 of SKS Hastane Sürüm 6.1. Standard-level references are verified for D2, D3, D5, D8, and D11; section-level verification was conducted for remaining dimensions. YBÜ = Yoğun Bakım Ünitesi; YBKÜ = Yenidoğan Yoğun Bakım Ünitesi; KBRN = Kimyasal, Biyolojik, Radyolojik ve Nükleer

scope, depth, and regulatory intent. The coding categories are analytical in character and are not evaluative; they do not constitute a judgment on the relative quality, comprehensiveness, or clinical effectiveness of either framework. A summary of the comparative mapping is presented in Table 4; detailed dimension-level mapping is provided in Supplementary Table 1.

The dominant pattern of Partial Convergence reflects a consistent finding across structural, clinical, information, measurement, and access domains: both frameworks address the same quality management functions, but through instruments that differ in genre, granularity, and regulatory mechanism. ISO 7101:2023 operates as a normative management system standard within a harmonised high-level structure, specifying requirements through "shall" obligations and leaving implementation methods to the organisation. SKS Hastane Sürüm 6.1 operates as a prescriptive national hospital quality standards framework, specifying standards and assessment criteria at the level of observable, surveyable hospital

Table 3 Coding categories and decision rules

Code	Category	Definition and decision rule	Applied to dimensions
FC	Full Convergence	Both frameworks contain requirements explicitly addressing the same quality domain using equivalent or near-equivalent constructs, with comparable levels of specificity. Correspondence is identifiable from document text without substantial inferential judgment.	Not assigned in this study
PC	Partial Convergence	Both frameworks address the same quality domain, but differ in scope, depth, conceptual framing, level of specificity, or degree of explicit requirement. The domain is identifiably shared, but treatment differs in at least one substantive dimension.	D1, D2, D3, D4, D5, D6, D8, D9, D10, D11, D12, D13, D14
ISO-D	ISO-Dominant Management System Emphasis	The domain is explicitly and substantially addressed in ISO 7101:2023, but is absent from or addressed only implicitly or incidentally in SKS Hastane Sürüm 6.1. Reflects documentary genre difference; not evaluative.	Not assigned in this study
SKS-D	SKS-Dominant Operational Specificity	The domain is explicitly and substantially addressed in SKS Hastane Sürüm 6.1 with dedicated sections and specific standards, but is absent from or addressed only at a higher level of abstraction in ISO 7101:2023. Reflects operational specificity and national context; not evaluative.	Not assigned in this study
COMP	Complementarity	Both frameworks address the same overarching domain but through approaches that are conceptually distinct and non-overlapping, such that requirements of one framework complement those of the other without substantial direct overlap.	D7
LEC	Limited Explicit Correspondence	The domain can be loosely or inferentially associated with content in both documents, but neither document explicitly addresses the domain in a directly comparable way. Correspondence relies substantially on interpretive inference.	Not assigned in this study
NDC	No Direct Correspondence	A quality domain present in one framework has no identifiable equivalent in the other document, after systematic review of the full text of both documents.	Not assigned in this study

Coding categories are analytical and non-evaluative. No category — including ISO-D and SKS-D — implies superiority, deficiency, or inadequacy in either framework. Differences in emphasis are interpreted as reflecting differences in framework genre, design purpose, and national context.

practice. These genre differences account for a substantial proportion of the partial rather than full convergence findings and should be understood as structural rather than substantive discrepancies.

Evidence depth across analytical dimensions

The fourteen analytical dimensions were not all mapped at the same level of evidentiary granularity, and this distinction is relevant to interpreting the results. Five dimensions — D2 (Leadership, Governance, and Accountability), D3 (Quality Planning and Strategic Objectives), D5 (Patient Safety and Risk Management), D8 (Information Management, Documentation, and Health Information Systems), and D11 (Measurement, Indicators, Monitoring, and Performance Evaluation) — were subjected to standard- and criteria-level verification, in which coding decisions were confirmed against specific SKS standard codes (e.g., KKY01–KKY10, KRY01–KRY05, DBY01–DBY17, GGİ01–GGİ07) and, where available, against individual assessment-criteria-level content. These five dimensions were prioritised for higher-depth verification because of their direct relevance to governance structures, patient safety, information management, and performance monitoring — areas where standard-level correspondence is most consequential for quality governance.

The remaining nine dimensions — D1 (Organisational Context and Scope), D4 (Patient/Person-Centred Care and Patient Experience), D6 (Workforce Competence, Training, and Healthy Working Life), D7 (Clinical and Service Delivery Processes), D9 (Resource, Infrastructure, Facility, Device, and Material Management), D10 (External Providers and Outsourced Services), D12 (Incident Reporting, Learning Systems, and Corrective and Preventive Action), D13 (Continuous Improvement and Quality Culture), and D14 (Accessibility, Equity, and Universal Health Coverage) — were mapped at section and domain level. Coding decisions for these dimensions were based on the identification of corresponding sections and domains within the SKS dimension and section structure and descriptive clause content in ISO 7101:2023, without standard- or criteria-level code verification. This distinction is explicitly represented in Table 4 and Supplementary Table 1. All fourteen dimensions were subjected to the same seven-category coding scheme; the distinction pertains solely to the depth of the evidentiary basis supporting the coding decision. Accordingly, the coding results should be interpreted as structured document-level convergence assessments, with stronger evidentiary depth for the five dimensions subjected to standard- and criteria-level verification.

Structural and governance-related domains (D1-D3)

Dimension 1: Organisational context and scope (PC)

ISO 7101:2023 addresses organisational context through Clauses 4.1 to 4.4, requiring organisations to determine internal and external factors influencing the quality management system (QMS), identify stakeholders and their requirements, define the formal scope of the management system, and establish the processes constituting the

Table 4 Summary comparative mapping of ISO 7101:2023 and SKS Hastane Sürüm 6.1 across 14 analytical dimensions

Dim.	Analytical dimension	ISO 7101:2023 clauses	SKS sections / standards	Code	Key analytical note	Evidence depth	Unresolved / partially unresolved items
D1	Organisational Context and Scope	Cl. 4.1–4.4	Kurumsal Yapı (KKU01-02)	**PC**	Both frameworks address organisational purpose, stakeholder orientation, and contextual goal-setting. ISO Cl. 4.3–4.4 formal QMS scope definition has no confirmed structural equivalent in SKS.	Section/ domain-level mapped	ISO Cl. 4.3–4.4 formal QMS scope definition; equivalent structural mechanism in SKS not confirmed at standard level.
D2	Leadership, Governance, and Accountability	Cl. 5.1–5.4	Kalite Yönetimi (KKY01-10); Kurumsal Yapı (KKU04-06)	**PC**	Standard-level verification confirmed quality policy (KKY01,Ç), Quality Directorate (KKY02,Ç), clinical governance (KKU04,Ç), and four mandatory governance committees (KKY06-10,Ç). ISO's 16-commitment leadership clause and 6-attribute quality policy are partially paralleled across distributed SKS standards.	Standard/ criteria-level verified	ISO Cl. 5.1's 16-point leadership construct spans multiple distributed SKS standards; unified construct not confirmed as single equivalent.
D3	Quality Planning and Strategic Objectives	Cl. 6.1–6.3	Kalite Yönetimi (KKY04,05,12); Kurumsal Yapı (KKU02-03); Kurumsal Verimlilik (KKV02-03) [public hospitals only]	**PC**	Both frameworks address risk-based planning and quality objectives. ISO Cl. 6.3 formal change management planning not confirmed as single equivalent SKS standard. Kurumsal Verimlilik restricted to public hospitals.	Standard/ criteria-level verified	ISO Cl. 6.3 formal change management planning; ISO Cl. 6.1.2 risk culture monitoring at defined intervals — not confirmed as single equivalent standards in verified SKS sections.
D4	Patient/Person-Centred Care and Patient Experience	Cl. 5.4; Cl. 8.10	Hasta Deneyimi; Yaşam Sonu Hizmetleri; Hasta Odaklılık	**PC**	Both frameworks address person-centred care as a core quality domain. ISO's management system framing differs from SKS's prescriptive, surveyable service-level standards.	Section/ domain-level mapped	Criteria-level correspondence between ISO person-centred care constructs and SKS Hasta Deneyimi/Hasta Odaklılık assessment criteria not verified.
D5	Patient Safety and Risk Management	Cl. 6.1.1–6.1.3; Cl. 8.12.1–8.12.9	Risk Yönetimi (KRY01-05,Ç); İstenmeyen Olay Bildirim Sistemi; KKY07,Ç (13 patient safety domains)	**PC**	Strong standard-level convergence confirmed across risk management governance (KRY01-05) and patient safety committee (KKY07). ISO risk culture monitoring (Cl. 6.1.2) and unified patient safety plan (Cl. 8.12.1) not confirmed as single equivalents in SKS.	Standard/ criteria-level verified	ISO Cl. 8.12.1 unified patient safety plan construct; ISO Cl. 6.1.2 risk culture monitoring — not confirmed as single equivalent SKS standards.
D6	Workforce Competence, Training, and Healthy Working Life	Cl. 7.2–7.3; Cl. 8.10.7	Eğitim Yönetimi; Çalışan Sağlığı ve Güvenliği; Sağlıklı Çalışma Yaşamı; KKY08-09,Ç	**PC**	Both frameworks address workforce competence, training, and occupational safety governance. Regulatory framing differs consistently with management system vs. prescriptive-criteria genre.	Section/ domain-level mapped	ISO Cl. 7.2 credentialing and privileging specificity; criteria-level correspondence with SKS Eğitim Yönetimi not verified at standard level.
D7	Clinical and Service Delivery Processes	Cl. 8.1; Cl. 8.7; Cl. 8.9; Cl. 8.11	Hasta Bakımı; Acil Servis; Ameliyathane; YBÜ; YBKÜ; Doğum; Laboratuvarlar; Kemoterapi; Palyatif Bakım (and further Sağlık Hizmetleri sections)	**COMP**	ISO provides management system architecture for service design, provision, and ethics governance. SKS provides operationally detailed, hospital-type-specific requirements across > 20 clinical sections. The two frameworks address clinical service delivery at complementary levels of abstraction and operational specificity.	Section/ domain-level mapped	Complementarity classification based on domain-level analysis; criteria-level mapping of individual clinical service sections not conducted.
D8	Information Management, Documentation, and Health Information Systems	Cl. 7.4.3; Cl. 7.5.1–7.5.6	Doküman Yönetimi (KDY01-02); Bilgi Yönetim Sistemi (DBY01-17); Tıbbi Kayıt ve Arşiv (DTA03-07)	**PC**	Comprehensive confirmed SKS framework including backup (DBY10,Ç: min. 3x daily, off-site), server security (DBY13,Ç), personal data protection (DBY05,Ç), and audit logging (DBY09). SKS operationally more specific than ISO in several sub-domains. ISO periodic records audit (Cl. 7.5.6) not confirmed as single equivalent.	Standard/ criteria-level verified	ISO Cl. 7.5.4 periodic records audit and ISO Cl. 7.4.3 privacy breach escalation — not confirmed as single equivalent standard-level requirements in SKS.

Table 4 (continued)

Dim.	Analytical dimension	ISO 7101:2023 clauses	SKS sections / standards	Code	Key analytical note	Evidence depth	Unresolved / partially unresolved items
D9	Resource, Infrastructure, Facility, Device, and Material Management	Cl. 7.1; Cl. 8.2; Cl. 8.4–8.6	Tesis Yönetimi; Malzeme ve Cihaz Yönetimi; Otelcilik Hizmetleri; Afet ve Acil Durum Yönetimi; KBRN Yönetimi	**PC**	Both frameworks address physical resource management. SKS KBRN extends emergency preparedness scope beyond ISO Cl. 8.2.2. ISO Cl. 8.5 (service user belongings) and Cl. 8.6 (emerging technology/AI) not confirmed at section level in SKS.	Section/ domain-level mapped	Criteria-level correspondence between ISO Cl. 8.2 and SKS Tesis Yönetimi/Cihaz Yönetimi assessment criteria not verified at standard level.
D10	External Providers and Outsourced Services	Cl. 8.8	Dış Kaynak Kullanımı	**PC**	Both frameworks include a dedicated section/clause for external provider governance. Criteria-level content of Dış Kaynak Kullanımı requires full coding for detailed equivalence assessment.	Section/ domain-level mapped	Criteria-level content of Dış Kaynak Kullanımı not verified; standard-level codes for this section not confirmed.
D11	Measurement, Indicators, Monitoring, and Performance Evaluation	Cl. 9.1–9.3	Göstergelerin İzlenmesi (GGİ01–07,Ç); Kalite Yönetimi (KKY04-05)	**PC**	Standard-level verification confirmed a detailed indicator management framework (GGİ01–07) with national reporting to Ministry of Health (GGİ07). ISO internal audit (Cl. 9.2) and 11-input management review (Cl. 9.3) addressed through structurally different documentary mechanisms in SKS (KKY04-05).	Standard/ criteria-level verified	ISO Cl. 9.2 internal audit (independence criteria, programme) vs. SKS KKY04 self-assessment (öz değerlendirme): functional overlap but conceptual distinction not resolved at criteria level. ISO Cl. 9.3 eleven-input management review vs. KKY05 not confirmed as criteria-level equivalent.
D12	Incident Reporting, Learning Systems, and Corrective and Preventive Action	Cl. 10.2	İstenmeyen Olay Bildirim Sistemi; Kalite Yönetimi (KKY12)	**PC**	Both frameworks address adverse event reporting, corrective action, and learning. SKS Terminoloji section defines Düzeltici-Önleyici Faaliyet and Kök Neden Analizi consistent with ISO Cl. 10.2.	Section/ domain-level mapped	Criteria-level correspondence between ISO Cl. 10.2 nonconformity/corrective action and SKS İstenmeyen Olay Bildirim Sistemi not verified at standard level.
D13	Continuous Improvement and Quality Culture	Cl. 5.1(d); Cl. 6.1.2; Cl. 10.1; Cl. 10.3	Kalite Yönetimi; Kurumsal Verimlilik; Sosyal Sorumluluk	**PC**	Continual improvement embedded in SKS's cyclical structure (self-assessment, evaluation meetings, improvement planning) paralleling ISO's PDSA orientation. ISO states continual improvement as a standalone normative obligation (Cl. 10.3).	Section/ domain-level mapped	ISO Cl. 6.1.2 risk culture construct within continual improvement domain not confirmed as single equivalent SKS standard. Criteria-level mapping not conducted.
D14	Accessibility, Equity, and Universal Health Coverage	Cl. 5.5; Cl. 8.10.4	Hizmete Erişim; Hakkaniyet (stated quality goal)	**PC**	Both frameworks address access and equity as quality principles. ISO's explicit UHC framing and financial risk minimisation requirements (Cl. 5.5) and SKS's access provisions operate within different regulatory and health system contexts.	Section/ domain-level mapped	ISO Cl. 5.5 equity and UHC framing; financial risk minimisation construct — not confirmed as standard-level requirements in SKS. Criteria-level mapping not conducted.

PC = Partial Convergence; COMP = Complementarity. Evidence depth: Standard/criteria-level verified = coding confirmed against specific SKS standard codes and assessment criteria; Section/domain-level mapped = coding based on section and domain identification without criteria-level verification. Shading: blue = PC dimensions; yellow = COMP dimension (D7). (Ç) = core standard (çekirdek) in SKS Hastane Sürüm 6.1

Note: Detailed clause/standard-level mapping, including ISO clause references, SKS section/standard references, coding rationale, and verification status for all dimensions, is provided in Supplementary Table 1

system. SKS Hastane Sürüm 6.1 addresses the equivalent domain primarily through the Kurumsal Yapı (Institutional Structure) section, which requires hospitals to define and publicly communicate mission, vision, and values, and to establish institutional goals in consideration of internal and external environmental factors and stakeholder expectations (KKU01, KKU02). The two frameworks converge on the identification of organisational purpose, goal-setting with contextual awareness, and stakeholder orientation. The convergence is classified as partial because ISO 7101:2023's explicit process-based scope definition (Cl. 4.3–4.4) within a harmonised management system architecture does not have a confirmed structural equivalent in the corresponding SKS section, reflecting the distinction between a scope statement as a management system artefact and the institutional governance structures reflected in SKS that define the operating context of hospitals.

Dimension 2: Leadership, governance, and accountability (PC)

ISO 7101:2023 addresses this domain through Clauses 5.1 to 5.4, specifying sixteen enumerated top management commitment requirements (Cl. 5.1a-t), a formal quality policy framework with six specified attributes (Cl. 5.2), eight accountability assignments (Cl. 5.3), and service user focus requirements at governance level (Cl. 5.4). Standard-level verification of SKS Hastane Sürüm 6.1 confirmed substantive convergence evidence.

The Kalite Yönetimi (Quality Management) section requires the hospital to establish a quality policy (KKY01, core standard [Ç]), with four top management commitments specified at assessment-criteria level, including alignment with quality goals, establishing and regularly reviewing quality objectives, meeting QMS requirements, and continual improvement of QMS effectiveness (KKY01.01-01.02). A Quality Directorate (Kalite Direktörlüğü) is required as a distinct organisational unit (KKY02, Ç) with a defined scope encompassing SKS coordination, objective tracking, self-assessment management, incident management, risk management, patient experience and staff surveys, document management, quality indicators, and committee participation (KKY02.04). Section quality officers are required across all hospital sections (KKY03, Ç). Clinical governance is explicitly required: KKU04 (Ç) requires its incorporation in the organisational chart, with defined processes for clinical process auditing, risk management, quality assurance, clinical effectiveness monitoring, and development activities (KKU06.01-06.04). Job descriptions with defined roles, responsibilities, conflict resolution procedures, and authority delegation are required for all units and staff (KKU05).

Four mandatory governance committees are required under KKY06: a patient safety committee (KKY07, Ç), a worker health and safety committee (KKY08, Ç), an education committee (KKY09, Ç), and a facility safety committee (KKY10, Ç), each convening at minimum four times per year (KKY06.04). Structured self-assessment at minimum biannual frequency is required (KKY04, Ç), with evaluation meetings including review of quality objectives and quality processes (KKY05.02) and planned improvement actions as a required output (KKY05.03). Corporate goals must be established considering internal and external factors including patient, staff, and community characteristics and feedback (KKU02.01).

The convergence is classified as partial because ISO Cl. 5.1's sixteen commitment requirements constitute a unified management system leadership construct; in SKS, the corresponding requirements are distributed across discrete standards and assessment criteria rather than expressed as a single equivalent normative requirement. ISO Cl. 5.2's full range of six quality policy attributes is only partially paralleled by the four commitments confirmed in KKY01.01. ISO Cl. 5.4's service user focus as a top management governance accountability is addressed in SKS through distributed standards (KKU02.01, KKY07) rather than a dedicated leadership accountability requirement.

Dimension 3: Quality planning and strategic objectives (PC)

ISO 7101:2023 addresses this domain through Clauses 6.1 to 6.3, requiring context-based risk and opportunity identification (Cl. 6.1.1), monitoring of risk awareness culture at defined intervals (Cl. 6.1.2), a risk register with defined criteria and severity ratings (Cl. 6.1.3), individually documented measurable quality objectives with responsible persons, resources, timeframes, and evaluation methods specified for each objective (Cl. 6.2), and formal change management planning (Cl. 6.3). Standard-level verification confirmed strategic quality planning requirements across two SKS sections. KKU02 requires corporate goals to be established considering internal and external factors (KKU02.01) with those goals serving as the basis for institutional activities (KKU02.02); KKU03 requires an action plan with specific implementation steps. KKY01.01 confirms a commitment to establishing and regularly reviewing quality objectives; KKY04's biannual self-assessment provides a structured monitoring cycle; KKY12 requires records of quality improvement activities and corrective and preventive action monitoring (KKY12.01-12.03). The Kurumsal Verimlilik (Institutional Efficiency) section provides an efficiency measurement framework with documented plans reviewed at minimum annually and measurement across eight defined domains (KKV02.01, KKV03.01); however, this section explicitly applies only to public

hospitals and cannot be treated as universal to the SKS framework in a mixed-sector analytical context. ISO Cl. 6.3's formal change management planning requirement was not confirmed as a single equivalent standard in any verified SKS section.

Patient/person-centred care, patient safety, and workforce domains (D4-D6)

Dimension 4: Patient/person-centred care and patient experience (PC)

ISO 7101:2023 addresses person-centred care through provisions for service user focus at governance level (Cl. 5.4), experience assessment (Cl. 8.10.2), health literacy (Cl. 8.10.5), co-production of care (Cl. 8.10.6), cultural inclusivity (Cl. 8.10.4), compassionate care (Cl. 8.10.3), end-of-life care, and patient rights and responsibilities (Cl. 8.9(b)), integrated within a management system architecture. SKS Hastane Sürüm 6.1 addresses patient-centred care through dedicated sections including Hasta Deneyimi (Patient Experience), Hasta Odaklılık (Patient Focus), and Yaşam Sonu Hizmetleri (End-of-Life Services), as well as patient rights requirements distributed across the Sağlık Hizmetleri (Health Services) dimension, and identifies Hasta Odaklılık (patient-centredness) as an explicit quality goal. Both frameworks converge on the principle of care responsiveness to patient preferences, experiences, and rights. The partial convergence classification reflects the difference between ISO's management system framing of person-centred care as a governance and policy commitment and SKS's prescriptive operationalisation through defined service-level standards and surveyable assessment criteria.

Dimension 5: Patient safety and risk management (PC)

ISO 7101:2023 addresses patient safety through normative definitions (Cl. 3.40–41), a risk-based planning framework (Cl. 6.1.1–6.1.3), and a nine-sub-clause patient safety operational framework (Cl. 8.12.1–8.12.9). Standard-level verification confirmed that SKS's Risk Yönetimi (Risk Management) section provides a comprehensive and structured risk management framework.

KRY01 (Ç) requires a hospital risk management board with defined responsibilities (KRY01.02), defined roles for conducting and reporting risk management activities (KRY01.03), and coordination with the Quality Directorate and committees (KRY01.04-01.05). KRY02 (Ç) requires risk management covering all hospital risk domains — medical, administrative, financial, technical, facility, environmental, and stakeholder communication — and all risk types including physical, chemical, biological, radiological, ergonomic, psychosocial, and service-related risks, with comprehensive documentation requirements. KRY03 (Ç) requires a documented risk management plan with structured content for each identified risk (process, risk level, actions, responsible persons, timeframe; KRY03.01); risk analyses at minimum every two years with defined triggers for earlier update (KRY03.04); a minimum three-tier risk level classification system (low, medium, high; KRY03.03); and coverage of after-hours processes (KRY03.05). KRY04 (Ç) requires improvement activities to eliminate or minimise identified risks, and KRY05 requires regular monitoring of their effectiveness.

The patient safety committee (KKY07, Ç) has an explicitly defined scope encompassing thirteen patient safety domains: patient identification, effective communication, medication safety, radiation safety, fall risk reduction, surgical safety, medical device safety, patient privacy, safe transfer, safe handoff, information security, infection prevention and control, and laboratory patient safety (KKY07.01). Two elements of ISO's patient safety domain were not confirmed as single equivalent requirements in the verified SKS sections: ISO Cl. 6.1.2's requirement to measure risk awareness culture at defined intervals (KRY05 addresses monitoring of intervention effectiveness, which is related but addressed through a different documentary mechanism); and ISO Cl. 8.12.1's unified patient safety plan requirement (SKS distributes patient safety governance across KKY07 and multiple clinical service sections).

Dimension 6: Workforce competence, training, and healthy working life (PC)

ISO 7101:2023 addresses workforce requirements through competence determination, education and training provision, documented competence evidence (Cl. 7.2a-j, including credentialing and privileging at Cl. 7.2f), awareness (Cl. 7.3), occupational safety, and employee wellbeing (Cl. 8.10.7). SKS Hastane Sürüm 6.1 addresses workforce through dedicated sections including Eğitim Yönetimi (Training Management) and Çalışan Sağlığı ve Güvenliği (Worker Health and Safety), together with section-specific competence and staffing requirements distributed across service sections. The worker health and safety committee (KKY08, Ç) covers risk reduction for staff, safety in high-risk areas, violence risk reduction, sharps injury risk, blood and body fluid exposure risk, and health screening programmes (KKY08.01). The education committee (KKY09, Ç) covers SKS quality training, in-service training, orientation training, and patient education (KKY09.01). Sağlıklı Çalışma Yaşamı (healthy working life) is included as an explicit quality goal in SKS. Partial convergence reflects alignment on core workforce quality functions alongside differences in regulatory framing consistent with the management system versus prescriptive-criteria genre distinction.

Clinical and service delivery processes (D7)

Dimension 7 was classified as Complementarity (COMP). ISO 7101:2023 addresses clinical and service delivery through Clauses 8.1 (operational planning and control of processes), 8.7 (service design in healthcare, across thirteen defined factors), 8.9 (twelve documented conditions for service provision, including patient rights, admission and registration, clinical recording, diagnostic and medication ordering, informed consent, specialist referral, care transfer, and discharge summaries), and 8.11 (ethics: identification, investigation, and addressing of ethical dilemmas, including workforce training on ethics and service user involvement in ethical decision-making).

SKS Hastane Sürüm 6.1 provides an extensive set of dedicated clinical service sections within the Sağlık Hizmetleri dimension, encompassing patient care (Hasta Bakımı), emergency services (Acil Servis), operating room services (Ameliyathane), intensive care (Yoğun Bakım Ünitesi), newborn intensive care (Yenidoğan Yoğun Bakım Ünitesi), childbirth services (Doğum Hizmetleri), clinical and non-clinical laboratory services, chemotherapy services, organ and tissue transplantation, dialysis, palliative care, home health services, physical therapy and rehabilitation, psychiatric services, community mental health services, and a range of further hospital-specific service areas.

The Complementarity classification reflects that both frameworks address clinical service delivery, but through instruments that are more accurately described as mutually reinforcing than structurally equivalent or non-overlapping. ISO 7101:2023 provides a management system architecture for the design, provision, and control of health services at domain level, specifying governance requirements applicable across service types. SKS Hastane Sürüm 6.1 specifies operationally detailed, hospital-type-specific requirements across a broad range of clinical service lines, providing surveyable criteria at the level of individual service processes and care episodes. The two frameworks together address clinical service delivery at complementary levels of abstraction and operational specificity.

Information, infrastructure, external providers, and support systems (D8-D10)

Dimension 8: Information management, documentation, and health information systems (PC)

ISO 7101:2023 addresses this domain through Clauses 7.4.3 (clinical communication and privacy), 7.5.1–7.5.3 (documented information scope, creation, and control), 7.5.4 (information management system requirements including cybersecurity risk), 7.5.5 (electronic health information control), and 7.5.6 (periodic records audit). Standard-level verification confirmed that the three relevant SKS sections — Doküman Yönetimi (KDY), Bilgi Yönetim Sistemi (DBY), and Tıbbi Kayıt ve Arşiv Hizmetleri (DTA) — together provide a comprehensive and operationally specific framework.

Doküman Yönetimi confirmed requirements for an eight-stage document management lifecycle (KDY01.01-01.05) and currency and version control with review dates, traceable changes, and intranet access to current documents (KDY02.01-02.03). The Bilgi Yönetim Sistemi section confirmed requirements for a hospital-wide information system policy (DBY01), periodic role and authorisation review (DBY02.02-02.03), an information system risk management programme at maximum six-month intervals covering physical threats, software and hardware issues, information security, privacy, and personal data protection (DBY03.01, DBY03.03), and comprehensive information security and personal data protection measures including access control, physical and environmental security, communication security, breach management, awareness training, and confidentiality agreements (DBY05, Ç). Backup requirements include minimum three daily backups, separate server storage, off-site physical storage in a different building, indefinite offline retention, and data recovery testing every six months (DBY10.02-10.06, Ç). Server room security requirements include physical access control, CCTV, fire suppression, UPS capacity, and temperature and humidity monitoring (DBY13, Ç). Transaction-level audit logging is required through a read-only database (DBY09.01). External access security is governed by a core standard requiring defined conditions, confidentiality agreements, and logging of all external access (DBY17, Ç).

The Tıbbi Kayıt ve Arşiv Hizmetleri section confirmed requirements for privacy and security in medical record access with authorisation rules, confidentiality obligations, and a breach management process (DTA03, DTA03.01); fixed patient file numbers across all visits, standard file content, and pre-archiving content checks (DTA04, Ç, DTA04.01-04.04); defined discharge summary content (DTA05.01-05.03); and archive operations management (DTA07). The convergence is classified as partial because ISO Cl. 7.5.6's structured periodic records audit was not confirmed as a single equivalent standard in the verified SKS sections; and ISO Cl. 7.5.5's ten requirements for electronic information control require criteria-level comparison for full equivalence assessment. Notably, the Bilgi Yönetim Sistemi sub-domain contains confirmed requirements more operationally specific than ISO Cl. 7.5.4 in several respects, including daily backup frequency, off-site storage provisions, recovery testing intervals, and server room physical security standards.

Dimension 9: Resource, infrastructure, facility, device, and material management (PC)

ISO 7101:2023 addresses this domain through Clauses 7.1 (resources) and 8.2.1–8.2.3 (healthcare facilities management and maintenance), 8.4 (handling and storage of materials), 8.5 (service user belongings), and 8.6 (emerging technologies). SKS Hastane Sürüm 6.1 provides dedicated sections including Tesis Yönetimi (facility management), Otelcilik Hizmetleri (hospitality services), Malzeme ve Cihaz Yönetimi (material and device management), Afet ve Acil Durum Yönetimi (disaster and emergency management), and KBRN Tehlikelerinin Yönetimi (chemical, biological, radiological, and nuclear hazard management). Both frameworks address physical resource, facility, equipment, and material management as substantive quality domains. SKS's KBRN Tehlikelerinin Yönetimi section extends the emergency preparedness domain beyond the general scope of ISO Cl. 8.2.2's contingency planning sub-clause, and SKS's Otelcilik Hizmetleri section addresses hospitality and support services not structured as a distinct sub-clause in ISO. ISO Cl. 8.5 (management of service user belongings) and Cl. 8.6 (emerging technology risk assessment, including artificial intelligence validation) are ISO-specific requirements without confirmed section-level equivalents in the reviewed SKS sections at this stage of the analysis.

Dimension 10: External providers and outsourced services (PC)

ISO 7101:2023 addresses external provider management through Clause 8.8, specifying six sub-requirements covering selection criteria, patient safety consideration, conformity verification, nonconformity communication, QMS alignment, and performance records. SKS Hastane Sürüm 6.1 includes a dedicated Dış Kaynak Kullanımı (Outsourcing/External Resource Use) section within the Destek Hizmetler (Support Services) dimension. The presence of a dedicated section in both frameworks addressing external provider governance provides structural evidence for partial convergence; criteria-level content of the Dış Kaynak Kullanımı section requires full coding for a detailed equivalence assessment at standard level.

Measurement, incident learning, and improvement domains (D11-D13)

Dimension 11: Measurement, indicators, monitoring, and performance evaluation (PC)

ISO 7101:2023 addresses performance evaluation through Clauses 9.1.1–9.1.4 (monitoring, measurement, analysis, and evaluation), 9.2.1–9.2.2 (internal audit), and 9.3.1–9.3.3 (management review). Standard-level verification confirmed that the Göstergelerin İzlenmesi (Indicator Monitoring) section of SKS provides a detailed and structured framework directly paralleling ISO Cl. 9.1.1–9.1.4.

GGİ01 (Ç) requires documented processes for measurement, evaluation, and improvement through quality indicators, covering indicator selection, data collection, data analysis, and post-analysis improvement planning, coordinated by the quality management unit (GGİ01.01–01.05). GGİ02 requires hospitals to determine quality indicators beyond SKS's own mandatory set, based on hospital structure, patient profile, and local priorities, with participation of section managers and quality officers (GGİ02.01–02.02). GGİ03 (Ç) requires a documented indicator card (gösterge kartı) for each indicator, specifying indicator code, definition, purpose, calculation method, sub-indicator, target value, data source, distribution list, data entry period, and responsible persons (GGİ03.01). GGİ04 requires defined data sources and collection processes using the health information system where possible (GGİ04.01–04.03). GGİ05 requires data analysis at defined intervals; GGİ06 requires improvement activities to be planned and implemented following analysis, with results shared with relevant staff (GGİ06.01); GGİ07 requires indicator results to be transmitted to the Ministry of Health's electronic database, providing a national-level reporting and benchmarking function not explicitly required as a distinct mechanism in ISO Cl. 9.1.

Complementary Kalite Yönetimi standards address internal assessment and management review functions. KKY04 (Ç) requires structured self-assessment (öz değerlendirme) at minimum biannual frequency, with top management briefed on identified nonconformities (KKY04.01, KKY04.04). KKY05 requires management evaluation meetings including review of quality objectives and quality processes, with planned improvement actions as a required output (KKY05.02-05.03). The convergence is classified as partial because SKS's self-assessment mechanism and evaluation meetings are not structurally identical to ISO Cl. 9.2's formal internal audit programme — which specifies auditor impartiality, a documented audit programme, and retained audit evidence — or to ISO Cl. 9.3's eleven defined management review input categories. Both mechanisms address comparable quality oversight functions through different documentary instruments, consistent with the normative management system versus prescriptive national standard genre distinction.

Dimension 12: Incident reporting, learning systems, and corrective and preventive action (PC)

ISO 7101:2023 addresses incident learning and corrective action through Clauses 10.1 and 10.2, requiring processes for nonconformity detection, containment, root cause analysis, corrective action, and documented evidence of

actions taken and their effectiveness. SKS Hastane Sürüm 6.1 addresses this domain through the İstenmeyen Olay Bildirim Sistemi (Adverse Event Reporting System) section and through quality improvement requirements in Kalite Yönetimi, including corrective and preventive action records (KKY12). The Terminoloji (Terminology) section of SKS includes explicit definitions of Düzelticiı-Önleyici Faaliyet (corrective and preventive action) and Kök Neden Analizi (root cause analysis), which align directly with ISO Cl. 10.2's corrective action framework. Partial convergence reflects alignment on the core incident learning function alongside differences in scope, structural depth, and documentary specificity.

Dimension 13: Continuous improvement and quality culture (PC)

ISO 7101:2023 addresses continual improvement through Clause 10.3, requiring the organisation to continually improve QMS suitability, adequacy, and effectiveness and to consider the outputs of analysis and evaluation in determining improvement opportunities; through Cl. 5.1(d) (creating a culture of quality); and through Cl. 6.1.2 (risk culture). SKS Hastane Sürüm 6.1 addresses the improvement domain through quality improvement activities in Kalite Yönetimi, the structured self-assessment cycle, committee governance, indicator-driven improvement processes, the Kurumsal Verimlilik (Institutional Efficiency) section, and the Sosyal Sorumluluk (Social Responsibility) section. The continual improvement function is embedded in the cyclical structure of SKS — self-assessment, evaluation meetings, improvement planning, and reassessment — which parallels the PDSA orientation of ISO's Clause 10 approach, though the two frameworks differ in how explicitly continual improvement is stated as a standalone normative obligation.

Accessibility, equity, and universal health coverage (D14)

Dimension 14: Accessibility, equity, and universal health coverage (PC)

ISO 7101:2023 references equitable, accessible, and people-centred care throughout its normative text, including service user focus (Cl. 5.4), quality objectives requiring consideration of health equity and cultural inclusivity (Cl. 6.2), access to care including affordability, accessibility, financial risk minimisation, and reference to United Nations Sustainable Development Goal 3.8 (Cl. 5.5), and inclusivity and diversity requirements in service design (Cl. 8.10.4). SKS Hastane Sürüm 6.1 addresses access and equity through the Hizmete Erişim (Access to Services) section within the Hasta ve Çalışan Odaklı Hizmetler dimension, and includes Hakkaniyet (equity) as an explicit quality goal. The partial convergence classification reflects a shared commitment to access and equity as quality values, while acknowledging that ISO's explicit universal health coverage framing as normative text requirements and SKS's access and equity provisions operate within different regulatory and health system contexts. The Turkish universal health coverage system context may account for the different framing of financial protection requirements; full equivalence at the standard and criteria level requires further coding.

Summary of unresolved and partially unresolved areas

Standard-level verification reduced the number of uncertain items for five of the fourteen dimensions (D2, D3, D5, D8, and D11); however, several items remained unresolved and are reported here to support transparency in the mapping evidence. ISO Cl. 6.3's formal change management planning requirement was not confirmed as a single equivalent standard in any verified SKS section (D3). ISO Cl. 6.1.2's requirement to measure risk awareness culture at defined intervals was not confirmed as a distinct SKS standard; KRY05 monitors the effectiveness of risk management interventions, which is related but addressed through a different documentary mechanism (D5). ISO Cl. 9.2's internal audit requirements are addressed in SKS through a structured self-assessment mechanism (KKY04, Ç) that performs a comparable oversight function through a structurally different instrument; criteria-level equivalence requires further verification (D11). ISO Cl. 9.3's eleven defined management review input categories constitute a structured review framework that may not be fully addressed by KKY05's evaluation meetings at criteria level (D11). ISO Cl. 7.5.6's structured periodic records audit was not confirmed as a single equivalent standard in the verified SKS sections (D8). The Kurumsal Verimlilik section's efficiency measurement framework is confirmed as restricted to public hospitals, introducing a relevant limitation when applying D3 findings in a mixed-sector analytical context. Detailed dimension-level mappings, coding rationales, evidence-depth classifications, and unresolved or partially unresolved items are provided in Supplementary Table 1.

Discussion

Principal findings

This qualitative document analysis compared ISO 7101:2023 and SKS Hastane Sürüm 6.1 across fourteen analytical dimensions. The principal finding is one of broad thematic overlap accompanied by systematic structural difference. Thirteen of the fourteen dimensions were classified as Partial Convergence and one — Dimension 7 (Clinical and Service Delivery Processes) — as Complementarity. No dimension was classified as Full Convergence or No Direct Correspondence. This pattern indicates that the two frameworks share a common

quality management agenda across structural, clinical, information, measurement, and access domains, while pursuing that agenda through substantially different documentary logics, levels of prescriptive detail, and regulatory mechanisms. ISO 7101:2023 constitutes a management system standard operating within a harmonised high-level structure, with requirements expressed as normative "shall" obligations applicable to any healthcare organisation, leaving the choice of implementation methods to the organisation. SKS Hastane Sürüm 6.1 constitutes a national hospital quality standards framework that translates quality management into prescriptive, surveyable standards and assessment criteria calibrated to the operational realities of hospitals in Türkiye. The convergence between these frameworks is, accordingly, a convergence of intent and domain scope rather than a convergence of method, granularity, or regulatory form.

Interpretation of partial convergence

Partial convergence does not indicate weakness or incompleteness in either framework; rather, it reflects differences in documentary genre, regulatory purpose, and level of prescriptive specificity. A management system standard and a national hospital quality standards framework are inherently distinct instruments: one establishes a governance architecture for organisational quality management systems, the other prescribes operational requirements that must be demonstrably met. The presence of partial rather than full convergence is therefore an expected structural consequence of comparing two frameworks with different regulatory mandates, not evidence of inadequacy in either.

The dominance of Partial Convergence across thirteen dimensions reflects a structural reality inherent to comparing a management system standard with a national hospital quality standards framework. Management system standards such as ISO 7101:2023 specify what an organisation must achieve without prescribing how those elements are operationalised. National hospital standards frameworks such as SKS Hastane Sürüm 6.1, by contrast, specify what a hospital must demonstrably have in place in terms that can be directly observed and scored by an evaluator. Partial Convergence therefore indicates that for each of the thirteen affected dimensions, both frameworks address the same substantive quality management function through instruments that differ in genre, specificity, and regulatory mechanism — not that either framework is deficient with respect to the other.

The single Complementarity classification for Dimension 7 reflects a related but distinct observation: both frameworks address clinical and service delivery processes, but at levels of abstraction and operational specificity that are substantially non-overlapping and potentially additive. ISO provides framework-level requirements for operational planning, service design, service provision conditions, and ethics governance; SKS provides a detailed catalogue of service-specific standards across more than twenty clinical sections within the Sağlık Hizmetleri dimension. It is also notable that no dimension produced a Full Convergence classification. This is consistent with the genre difference described above and should not be interpreted as indicating weak or insufficient alignment. The goal of quality assurance systems is to improve patient outcomes and organisational performance, not to replicate each other's documentary architecture.

SKS Hastane Sürüm 6.1 as an operational national hospital quality infrastructure

The findings of this study provide documentary evidence that SKS Hastane Sürüm 6.1 constitutes a comprehensive and operationally detailed quality standards framework. Standard-level verification for five critical dimensions confirmed the presence of specific, surveyable requirements across governance, risk management, information management, and performance measurement domains. In the governance domain (D2), confirmed requirements include a hospital quality policy with top management commitments (KKY01, Ç), a Quality Directorate with a defined organisational scope (KKY02, Ç), section quality officers across all hospital sections (KKY03, Ç), biannual structured self-assessment (KKY04, Ç), and four mandatory governance committees each meeting at minimum four times per year (KKY06-10, Ç). Clinical governance is explicitly required as a structural element (KKU04, Ç), with defined processes for clinical process auditing, risk management, quality assurance, clinical effectiveness monitoring, and development activities (KKU06.01-04). These requirements collectively provide a governance architecture that is operationally specific in a way that management system requirements, by design, are not.

In the patient safety and risk management domain (D5), standard-level verification confirmed a five-standard Risk Yönetimi framework including a formal hospital risk management board (KRY01, Ç), risk management covering all hospital risk domains and risk types (KRY02, Ç), a structured risk management plan with a minimum three-tier risk classification system (KRY03, Ç), improvement activities (KRY04, Ç), and regular monitoring of effectiveness (KRY05). The patient safety committee (KKY07, Ç) has an explicitly defined scope covering thirteen patient safety domains. In the information management domain (D8), confirmed requirements for daily backup frequency (minimum three per day), offsite physical storage, six-monthly data recovery testing, and server room physical security (DBY10, DBY13, Ç) are more operationally specific than the corresponding management system-level requirements in ISO Cl.

7.5.4. In the measurement and performance evaluation domain (D11), the national reporting function (GGİ07) extends performance monitoring beyond the individual hospital to a system-level benchmarking mechanism not explicitly required as a distinct construct in ISO Cl. 9.1. Taken together, these findings suggest that SKS Hastane Sürüm 6.1 functions as a comprehensive operational quality infrastructure for hospitals in Türkiye, addressing the same quality management domains as ISO 7101:2023 through a prescriptive, hospital-type-specific, and nationally calibrated instrument. Its operational specificity is a feature of its design and intended function, not a limitation relative to international management system standards.

ISO 7101:2023 as a complementary management-system lens

The results do not support a conclusion that ISO 7101:2023 addresses quality domains not covered by SKS Hastane Sürüm 6.1. They do indicate that ISO 7101:2023 frames several quality management constructs at a structural level that may complement the operational specificity of SKS without duplicating it. These include formal organisational context analysis (Cl. 4.1–4.4), explicit scope definition for the management system (Cl. 4.3), structured leadership accountability across sixteen confirmed commitments (Cl. 5.1), a quality policy framework with six specified attributes (Cl. 5.2), eight formal accountability assignments (Cl. 5.3), and service user focus at governance level (Cl. 5.4). ISO 7101:2023's planning provisions — measurable quality objectives with individually documented responsible persons, resources, timeframes, and evaluation methods (Cl. 6.2), and formal change management planning (Cl. 6.3) — represent planning instruments with a level of structural documentation not confirmed as a single equivalent standard in the verified SKS sections. Similarly, ISO Cl. 6.1.2's requirement to monitor risk awareness culture at defined intervals introduces a measurement construct oriented toward organisational culture that differs from the confirmed scope of KRY05. The internal audit programme (Cl. 9.2) and the eleven-input management review (Cl. 9.3) provide a structured cyclical evaluation architecture that, while functionally paralleled by SKS's self-assessment (KKY04) and evaluation meetings (KKY05), operates through different mechanisms with different documentary requirements. These observations reflect that the two frameworks embody different theories of how quality management standards should be designed — one centred on a transferable, sector-agnostic management system architecture; the other centred on nationally calibrated, operationally specific hospital standards that can be directly surveyed and scored — not that either approach is inherently superior.

Workforce competence and occupational health and safety in structural perspective (Dimension 6)

The sixth dimension (Workforce Competence, Training and Healthy Working Life) is highly representative of the general management-system architecture of ISO 7101:2023 and of the specific workings of SKS Hastane Sürüm 6.1 and is particularly illustrative because it addresses worker health and safety issues. Highly specific, SKS describes worker health and safety in the format of established data. The worker health and safety committee of SKS (KKY08 in Ç) has a specific area of responsibility: violence risk reduction, sharps injury risk, risk of exposure to blood and body fluids, staff safety in high-risk areas, and occupational health screening programmes. The education committee (KKY09 in Ç) has a specific area of responsibility: orientation and in-service training (KKY09.01). ISO 7101:2023 does not repeat those operational hazards but specifies management-system requirements for leadership responsibility (Cl. 5.1, Cl. 5.3), and competence and awareness requirements (Cl. 5.2), communication requirements (Cl. 7.4), and documentation requirements (Cl. 7.5). 7.2–7.3), risk-based planning (Cl. 6.1.1–6.1.3), monitoring and review processes (Cl. The general obligations for continual improvement (Cl. 9.1–9.3) and continual improvement as a standalone obligation (Cl. 10.3) apply to all the quality areas, including occupational health and safety.

Read together, ISO's generic mechanisms could operationalize SKS's worker health and safety requirements in several different ways, each of which is suggested by document structure and requires an empirical investigation to be clarified. ISO's leadership responsibility provisions (Cl. 5.1, Cl. 5.3) could identify opportunities to include management of violence risk reduction, sharps injury prevention, and control of exposure to blood and body fluids as a governance requirement to complement the corporate committees, or equivalent, described in the governing documents (ISO's competence and awareness requirements). 7.2–7.3) can provide additional governance to SKS's orientation and in-service training requirements (KKY09), for example by requiring documented evidence that staff competence in high-risk areas has actually been assessed and not merely delivered as training content. ISO's risk-based planning (Cl. 6.1.1–6.1.3), including its periodic (optional) need to monitor risk awareness culture, may support the safety and screening requirements of SKS's staff (KKY08.01) by embedding them in an organization-wide risk register rather than as a committee-level work plan. ISO's monitoring and review clauses (Cl. In contrast, Clauses 9.1–9.3, and continual improvement (Cl. 10.3) may then provide the means to review the effectiveness of SKS's occupational health screening, safety and other quality

aims and objectives, the progress made and any areas needing improvement.

This discussion of structural parallels should not be read as saying that ISO 7101:2023 will give better working health and safety outcomes than SKS's other systems, or that SKS's other systems are insufficient, as that would be much better justified at a higher level. Rather, ISO's requirements for leadership, competence, planning, monitoring, and improvement may give the governance structure needed to bring SKS's already-strong requirements together into a coherence built from a single architecture of accountability and review. Whether implementation of such an integrated system in Turkish hospitals would reduce violence, sharps injuries, or blood and body fluid exposures, or just add a further layer of documentation, is an empirical question not answerable by this document analysis.

Areas where alignment may require careful interpretation

Several analytical dimensions produced items not fully resolved through standard-level verification that may require careful interpretation in any practical alignment effort. ISO Cl. 6.3's formal change management planning requirement was not confirmed as a single equivalent standard in any verified SKS section; change management activities may be addressed implicitly within SKS's planning and improvement processes, but this could not be confirmed from the sections reviewed. ISO Cl. 6.1.2's risk awareness culture measurement construct differs from the confirmed scope of KRY05 and requires full criteria-level coding of additional sections to determine whether it is addressed elsewhere in the framework.

The relationship between ISO Cl. 9.2's internal audit programme and SKS's öz değerlendirme (self-assessment, KKY04, Ç) merits particular attention for any practical alignment effort. Both mechanisms provide a structured, periodic evaluation of QMS conformity, but are designed on different principles: external evaluative criteria and independence requirements in ISO versus internally coordinated, frequency-specified self-review in SKS. These differences are consistent with the different regulatory contexts and purposes of the two frameworks and should be understood as differences of instrument rather than of intent. ISO Cl. 9.3's management review, specifying eleven defined input categories and documented output requirements, operates through a more structurally specified mechanism than KKY05's evaluation meetings; whether all eleven input categories are addressed across KKY05 criteria-level requirements requires further verification. The Kurumsal Verimlilik section's scope restriction to public hospitals is a material consideration for any analysis that seeks to generalise D3 findings to the full spectrum of hospital types to which ISO 7101:2023 would apply.

Potential administrative burden of overlapping mechanisms

That said, a final, document-level observation that has not yet been addressed is administrative load that could result from operating overlapping quality-oversight mechanisms in parallel. The most illustrative example would be the functioning of ISO Cl. 9.2 internal audit programme and SKS's KKY04 self-assessment (öz değerlendirme, Ç) in parallel. The systematic, periodic review of conformity specified by these controls is very similar in function. It is formally specified, but differently documented (ISO requires auditor independence and a documented audit program; SKS specifies bi-annual self-assessment and top-management briefing); an institution that separated these processes into two sequential processes would incur increased documentation burden, audit fatigue of its clinical and quality personnel, redundant evidence collection for what is substantively the same conformity question, and increased administrative burden for its quality units that support the SKS's committee structure, indicator system, and self-assessment cycle.

However, this administrative burden can be reduced by using an integrated audit and self-assessment calendar (for example scheduling the ISO-style internal audit activity and the SKS biannual self-assessment as a single activity), a single shared evidence base (evidence collected to support one mechanism, ISO-style audit records, indicator records GGİ01–07, corrective action records KKY12, could be reused to support SKS assessment), aligning indicator and corrective action monitoring of the two systems, risk based allocation of audit and self-assessment resources to the areas where the organization is exposed to the highest risk, rather than splitting the time between the ISO-style audit and the SKS biannual self-assessment, and using digital documentation systems that allow the same documentation effort to support both the ISO-style audit trail and the SKS self-assessment record.

The above discussion of administrative burden and strategies for reducing it is a hypothesized finding based on inspection of the regulatory oversight regimes of the two frameworks. No data were taken on the actual times taken to complete documentation, nor on staff workload nor audit fatigue experienced by any of the hospitals. Although the strategies mentioned above have not been tested in this study, empirical studies comparing the actual administrative burden of the separate implementation of an ISO-style internal audit and implementation of an SKS self-assessment with the burden of their joint implementation could provide an answer to the question of whether such a burden exists at all and how great it is.

Implications for health services management and policy

The findings of this study may inform several areas of health services management practice and quality policy, subject to the important caveat that document-level analysis cannot substitute for empirical assessment of implementation effectiveness. For hospital quality directors and quality management professionals, ISO 7101:2023's management system constructs — particularly organisational context analysis, measurable quality objectives with formally documented planning elements, and the management review input framework — may provide a supplementary analytical vocabulary for structuring quality improvement activities beyond the immediate requirements of the SKS assessment cycle. Whether such complementary use could be achieved in practice, and what its effects might be on quality outcomes, requires empirical investigation.

For national quality authorities and hospital quality assessment bodies, the partial convergence findings suggest that the two frameworks are not in substantive conflict and that the existing SKS Hastane Sürüm 6.1 framework already addresses the majority of quality management domains that ISO 7101:2023 covers. Any future alignment effort may therefore not require wholesale revision of the national framework but may instead focus on the specific management system constructs identified as less explicitly articulated in the current SKS structure. Such an effort would require detailed criteria-level comparison and would need to involve relevant regulatory, clinical, and managerial stakeholders.

For hospital quality professional training, familiarity with both the operational requirements of SKS Hastane Sürüm 6.1 and the management system principles of ISO 7101:2023 may equip quality professionals with a broader analytical toolkit. The development of training curricula drawing on both frameworks without requiring simultaneous compliance with both systems may represent a pragmatic approach in contexts where both frameworks are institutionally relevant.

Implications for future research

This study identifies several directions for future research. Empirical implementation studies examining how hospitals operating under SKS Hastane Sürüm 6.1 address in practice the quality management functions identified in this comparative mapping would provide evidence about whether the partial convergences identified at document level translate into comparable outcomes at operational level. Qualitative research involving hospital quality directors, quality management professionals, and Ministry of Health evaluators could explore how practitioners experience the two frameworks in practice. Case studies of hospitals that have simultaneously pursued SKS assessment and ISO 7101:2023 or related ISO 9001 certification could provide direct evidence of how the two frameworks interact at the organisational level. Comparison of other subsets of the SKS framework with ISO 7101:2023 would provide a more comprehensive picture of convergence patterns across the full scope of Turkish health services. Cross-national comparative analyses examining how other national hospital quality standards frameworks relate to ISO 7101:2023 would contextualise the current findings within the international healthcare quality literature.

Another direction for future work would be to validate the Partial Convergence classifications. In the current study, the coding for Partial Convergence was done via a reflexive self-audit by the single author, rather than independently coded by multiple raters. Further work could confirm and strengthen their reliability by using panels of hospital quality experts and standards developers in Delphi or modified-Delphi consensus exercising, or as independent coders using the seven-category scheme to classify the same set of dimensions and then assessing inter-rater agreement. This systematic multi-rater approach would not be expected to undo the broad pattern of thematic overlap seen here, but would strengthen the reliability, interpretive robustness and external validation of the dimension-level classifications. It would also lay a better methodological foundation for this kind of comparative standards mapping to be used in health services research generally.

International relevance and methodological transferability

While this article's empirical object is Türkiye's SKS Hastane Sürüm 6.1, the analysis is likely of broader interest given the variety of hospital quality standards and accreditation schemes in operation worldwide. Also gaining international traction is ISO 7101:2023, a generic standard on quality management systems in all sectors, for healthcare quality. Related organizations overseas, including quality authorities, hospital accreditation agencies and health services researchers, wanting to know how their national system compares with ISO 7101:2023, are in a structurally similar position to this realization, faced with two documents based on different logics that cannot be accurately compared without an analytical instrument in-between.

Despite the fact that the fourteen dimension mapping framework and seven category coding scheme in this study were derived from the content domains occurring within the international health services quality literature rather than from the SKS Hastane Sürüm 6.1 specifications, this methodological model may yet be helpful in other countries' comparisons of their own national hospital quality frameworks with ISO 7101:2023 or with other national hospital quality frameworks. It would require country-specific work, however, in that operational

definitions of each dimension (and certainly content mapping) need to be re-derived from the national framework under study. This study does not claim that the results from the Turkish framework of SKS Hastane Sürüm 6.1 are necessarily entirely reproducible with the frameworks from other countries or that the fourteen-dimension framework would be entirely reproducible without modification, but it does claim that the overall method of triangulation of clause structure, national standards framework and quality domains from the literature into a predetermined and fixed set of dimensions may be useful elsewhere.

Strengths and limitations

This study has several methodological strengths. The analysis was conducted directly from primary source documents rather than from secondary summaries, ensuring that findings are traceable to the primary regulatory and standards texts. A transparent, pre-specified seven-category coding scheme was applied across fourteen analytical dimensions, providing a structured and replicable analytical framework. Standard-level verification was conducted for five critical dimensions, substantially increasing the evidentiary basis for those dimensions. The comparison was designed explicitly as non-hierarchical: coding categories are analytical rather than evaluative, and neither framework is treated as the reference standard against which the other is measured.

The study has limitations that qualify the scope and generalisability of the findings. First, the analysis is conducted at the document level and cannot address how the frameworks are implemented in practice, what outcomes they produce, or whether implementation of one framework supports or impedes the other; document-level findings must not be interpreted as evidence of implementation effectiveness or quality outcomes. Second, this study does not include any empirical implementation data or quality outcome data; all findings derive exclusively from analysis of the primary documents themselves. Third, the study was conducted by a single author without independent inter-rater coding; the structured self-audit, decision log, and transparent reporting of unresolved items address but do not fully substitute for this limitation. Fourth, standard- and criteria-level verification was completed only for five of the fourteen analytical dimensions (D2, D3, D5, D8, and D11); the remaining nine dimensions were mapped at section and domain level, which provides a less granular evidentiary basis for the coding decisions assigned to those dimensions. Fifth, ISO 7101:2023 is a copyrighted document; extensive quotation is not permissible and all ISO content is paraphrased with clause references, which may reduce the verbatim verifiability of specific ISO claims. Sixth, translation between Turkish and English introduces conceptual equivalence challenges; English translations of Turkish SKS terminology are the author's own and may not precisely reflect all connotations of the original. Seventh, the scope of the SKS component is limited to SKS Hastane Sürüm 6.1; other SKS document sets applicable to different care settings were not included, and the findings should not be generalised to the full SKS programme or non-hospital settings. Eighth, the findings may become outdated if ISO 7101:2023 or SKS Hastane Sürüm 6.1 is revised; document-level comparative analyses are inherently time-sensitive. Ninth, this study does not evaluate the comparative effectiveness of ISO 7101:2023 and SKS Hastane Sürüm 6.1 as quality improvement instruments; coding categories describe documentary relationships only, not performance outcomes or organisational effectiveness. Tenth, the targeted contextual literature search was not a formal systematic review, and the possibility that relevant comparable analyses exist but are not indexed in the databases searched cannot be excluded.

Despite these limitations, the study provides a methodologically transparent, primary-document-based comparative analysis that addresses a previously unexamined aspect of health quality governance in Türkiye. The analytical framework, decision rules, and supplementary mapping matrix provide a documented foundation that future researchers, quality professionals, and policy analysts may inspect, challenge, and build upon.

Overall interpretation

The evidence from this qualitative document analysis supports an interpretation of ISO 7101:2023 and SKS Hastane Sürüm 6.1 as potentially complementary rather than competing frameworks for hospital quality governance. The two frameworks differ fundamentally in their regulatory form, genre, and level of prescriptive specificity — differences that are by design and that reflect the distinct purposes each framework is intended to serve. SKS Hastane Sürüm 6.1 offers operationally grounded, nationally calibrated hospital quality specificity: confirmed standards for governance committees, risk management boards, patient safety domains, information security, indicator cards, national reporting, and a range of clinical service areas. ISO 7101:2023 offers a different but related analytical register: management system coherence expressed through organisational context analysis, formal scope definition, leadership accountability architecture, quality policy requirements, measurable objective documentation, risk-based planning including change management, internal audit with defined independence criteria, structured management review, and continual improvement as a normative obligation. Understanding these frameworks as potentially complementary has implications for hospital quality governance, quality professional training, and national quality policy,

but the translation of document-level complementarity into practical integration would require careful empirical assessment of how the two systems interact at the organisational level.

Conclusions

This qualitative document analysis examined the relationship between ISO 7101:2023 and SKS Hastane Sürüm 6.1 across fourteen analytical dimensions. The findings indicate broad thematic overlap across hospital quality domains at the document level: thirteen dimensions were classified as Partial Convergence and one — covering clinical and service delivery processes — as Complementarity. No dimension produced a Full Convergence classification, a result that reflects the fundamental difference in documentary form between a harmonised management system standard and a nationally calibrated hospital quality standards framework rather than a deficiency in either instrument.

SKS Hastane Sürüm 6.1 constitutes a comprehensive operational quality infrastructure for hospitals in Türkiye, providing prescriptive, surveyable standards and assessment criteria across governance, patient safety, risk management, clinical services, information management, and performance measurement domains. Standard-level verification confirmed the depth and operational specificity of the framework across five critical dimensions, including structured governance committee requirements with defined meeting frequencies, a five-standard risk management architecture with core designations, and a national indicator monitoring system with reporting to the Ministry of Health electronic database.

ISO 7101:2023 offers a complementary management-system architecture that addresses several constructs at a structural level not fully replicated in the prescriptive hospital standards format of SKS. These include formal organisational context analysis, explicit scope definition for the quality management system, structured leadership accountability across sixteen confirmed commitments, measurable quality objectives with formally documented planning elements, change management planning, risk awareness culture monitoring, a structured internal audit programme with independence criteria, an eleven-input management review, and continual improvement as a standalone normative obligation.

The two frameworks should be understood as potentially complementary rather than competing: they pursue a shared quality management agenda through instruments designed for different regulatory purposes, levels of prescriptive specificity, and implementation contexts. This potential complementarity may inform future work on hospital quality governance, quality professional development, and national quality policy in Türkiye, particularly in contexts where alignment with international management system standards is of strategic interest. The findings of this study are based on document-level analysis and should not be interpreted as evidence about the comparative effectiveness of the two frameworks in improving hospital quality outcomes. Empirical research examining how these frameworks interact in hospital practice — including implementation experience, quality indicator outcomes, and practitioner perspectives — is needed before firm conclusions about the practical value of alignment can be drawn.

Beyond its immediate relevance to Türkiye, the fourteen-dimension mapping framework and seven-category coding scheme developed for this analysis may offer a transferable methodological template for other countries seeking to examine how their own national hospital quality standards relate to ISO 7101:2023, without implying that the specific findings reported here generalise beyond the Turkish case examined.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-026-15273-9.

Supplementary Material 1

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Author contributions
FK conceived and designed the study, collected and analyzed the documents/data, interpreted the findings, wrote the original manuscript, revised the manuscript critically for important intellectual content, and approved the final version of the manuscript.

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Data availability
The data supporting the findings of this study consist of the documentary sources analysed and the comparative coding outputs generated during the study. SKS Hastane Sürüm 6.1 is available through the official channels of the Republic of Türkiye Ministry of Health. TS ISO 7101:2023 was accessed through the Turkish Standards Institution as an authorised national standards body and is subject to copyright restrictions. The complete analytical mapping and coding outputs are provided in Supplementary Table 1.

Declarations

Ethics approval and consent to participate
Not applicable. This study was based exclusively on document analysis and did not involve human participants, personal data, clinical data, or animal subjects.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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