

# Risk-Based Accreditation Governance in European Hospitals: A Maturity Framework for Transitioning from Compliance to Organizational Learning\*

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## Abstract

**Purpose:** This paper reframes hospital accreditation in European healthcare from compliance documentation into continuous risk-based governance.

**Design / Methodology / Approach:** A structured narrative synthesis (2010–2026) drawn from PubMed/PMC, Scopus, and OpenAlex informed conceptual framework development following Jaakkola (2020) and Whitemore and Knafl (2005). The paper is explicitly a conceptual contribution and does not constitute a systematic review.

**Findings:** Accreditation effects are stronger on processes, safety culture, and managerial routines than on isolated clinical outcomes. The implementation gap is the disconnection between risk identification, board accountability, incident learning, performance monitoring, and the information infrastructure operationalizing them.

**Originality / Value:** The paper proposes the **Risk-Based Accreditation Governance (RBAG) Framework**, a four-dimension, three-maturity-level model. Unlike MaPSaF and AHRQ SOPS 2.0, which treat safety culture in isolation, RBAG specifies the architectural integration between accreditation evidence, risk governance routines, and the information layer enabling Level 3 maturity. The framework draws on ISQua 6th Edition (2025), ISO 7101:2023, COSO ERM, IIA Three Lines, and WHO guidance on AI governance (2021b, 2024).

**Practical Implications:** The framework offers a diagnostic for managers, accreditation bodies, and policymakers, clarifying digital infrastructure and AI-enabled surveillance as enablers of governance maturity.

**Keywords:** hospital accreditation; risk governance; patient safety; European healthcare management; organizational learning; information governance; AI in healthcare

## Introduction

Hospital accreditation is among the most widely deployed quality improvement mechanisms in European healthcare. Mandatory or voluntary programmes operate across most EU and EEA states: the Haute Autorité de Santé (HAS) in France, Kooperation für Transparenz und Qualität im Krankenhaus (KTQ) in Germany, Centrum Monitorowania Jakości (CMJ) in Poland, and Autoritatea Națională de Management al Calității în Sănătate (ANMCS) in Romania. ISQua, through its External Evaluation Association, sets meta-accreditation standards (ISQua EEA, 2025).

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Despite adoption, evidence is mixed: systematic reviews find accreditation produces stronger effects on processes, documentation, and safety culture than on patient outcomes directly (Flodgren et al., 2016; Hussein et al., 2021). The primary mechanism is not the content of standards but the organizational routines accreditation triggers, or fails to trigger, around risk identification, accountability, incident learning, and performance monitoring (Braithwaite et al., 2017; Macrae, 2014).

Recent policy shifts make this challenge timely: ISQua 6th Edition Principles (2025), mandatory from July 2026, ISO 7101:2023, the WHO Global Patient Safety Action Plan 2021–2030 (WHO, 2021a), and WHO guidance on AI governance for health (2021b, 2024) all require accreditation to integrate clinical, organizational, and information governance, including the accountability mechanisms for AI-enabled decision support that current frameworks do not adequately specify (Macrae, 2019; Char et al., 2020).

This paper addresses the following research question:

**RQ:** *How can hospital accreditation in European healthcare systems be operationalized as a risk-based governance mechanism rather than a periodic compliance exercise, and what organizational maturity dimensions — including information and algorithmic governance — characterize this transition?*

The contribution is the **Risk-Based Accreditation Governance (RBAG) Framework**: a conceptual model with four governance dimensions and three maturity levels through which hospitals can diagnose their position and plan a transition toward governance-based accreditation. Unlike prior maturity instruments focused on safety culture as a standalone construct, RBAG specifies the architectural integration between accreditation evidence and the risk, information, and algorithmic governance routines that enable sustained improvement. The model is illustrated with vignettes from four European accreditation systems, including a transitional case from Eastern Europe.

## Literature Review

### *Hospital Accreditation in Europe: Landscape and Limitations*

European hospital accreditation spans mandatory systems (France, since 1996) to purely voluntary signals (Germany, Austria, Nordics). Comparative analysis identifies heterogeneity in standards content, methodology, funding, and legal status, with limited cross-national comparability (Groene et al., 2010; Lam et al., 2018). Hospitals may achieve accreditation under divergent criteria while sharing similar underlying risk management deficits.

Evidence on effectiveness is mixed but directionally consistent. Flodgren et al. (2016) found improvements in organizational processes but insufficient evidence on patient outcomes. Hussein et al. (2021) found a positive but heterogeneous association, dependent on culture, leadership, and risk system maturity. Braithwaite et al. (2017) identified the "accreditation milieu", the organizational environment surrounding the cycle, as more predictive than standards content, suggesting governance mediates accreditation effects.

### *Risk Management and Governance Architectures*

Enterprise risk management (ERM) in healthcare has shifted from insurance and liability frameworks toward strategic and clinical risk integration (Carroll, 2016). COSO (2017) updated its ERM framework to integrate risk with strategy and performance, a logic increasingly applied to healthcare governance. The IIA Three Lines Model (IIA, 2020) provides a complementary architecture: first line (operational and clinical teams) owns risk; second line (quality, compliance, patient safety) provides standards, monitoring, and challenge; third line (internal audit) provides independent assurance to the governing body, which sets risk appetite.

OECD (2023) documents persistent gaps in operationalization across European systems, particularly the disconnection between board-level strategic discussion of risk and operational data from incident reporting. Accreditation surveys typically assess the existence of risk management documentation rather than its integration into decision-making (WHO, 2018).

### *Safety Culture, Incident Learning, and the Limits of Just Culture*

Safety culture is connected to accreditation outcomes. The AHRQ Hospital Survey on Patient Safety Culture (SOPS 2.0) identifies management support, supervisor expectations, communication openness, and non-punitive response to error as predictors of safety performance (AHRQ, 2019). Westrum's (2004) typology (pathological, bureaucratic, generative) provides a developmental frame aligned with the maturity logic adopted here.

Reason's (1997, 2000) Swiss Cheese Model established how systemic factors combine to produce adverse events. Marx's (2001) Just Culture framework operationalizes this by distinguishing human error, at-risk behaviour, and reckless behaviour, calibrating accountability so reporting can function without excessive blame. Vincent (2010) and Vincent and Amalberti (2016) connect risk identification to learning and governance accountability through the *Safer Healthcare* model.

Dekker (2007, 2014) argues that the binary classification of behaviour is susceptible to retrospective bias and managerial discretion. The *restorative just culture* approach (Dekker, 2018) reframes the response to incidents around the repair of trust, learning, and accountability relationships rather than behavioural classification. RBAG adopts this nuance: a Level 3 incident learning system is defined by the demonstrable functioning of restorative learning routines, not by Just Culture vocabulary.

### ***Existing Maturity Frameworks: What RBAG Adds***

Several maturity frameworks exist. The **Manchester Patient Safety Framework (MaPSaF)** (Kirk et al., 2007; Parker, 2009) specifies five maturity levels across ten dimensions of safety culture, widely used in the UK NHS. The **AHRQ SOPS 2.0** (AHRQ, 2019) provides composite culture scores, often used developmentally; Singer et al. (2003) offers a similar instrument. At the digital level, the HIMSS Electronic Medical Record Adoption Model (EMRAM) specifies maturity in digital infrastructure (HIMSS, 2024) but does not address accreditation or clinical risk governance.

These frameworks share a limitation: they assess **safety culture or digital maturity as standalone constructs**, separate from the formal governance architecture (board accountability, three lines, risk appetite) through which hospitals demonstrate compliance. Hospitals scoring highly on cultural maturity may still produce evidence in a documentation-driven mode, and hospitals with mature digital infrastructures may not have integrated it into risk governance routines.

RBAG specifies the **architectural integration** between accreditation evidence, risk governance routines, and the supporting information infrastructure. Rather than measuring culture or technology in isolation, it describes how risk architecture, governance accountability, incident learning, and performance monitoring jointly mature toward governance-integrated accreditation. Three levels are adopted following Westrum's (2004) typology, prioritising parsimony.

### ***The Policy Convergence: ISQua 6th Edition, ISO 7101, and AI Governance***

Three policy developments make this contribution timely. ISQua's 6th Edition Principles (2025), mandatory from July 2026, replace numerical scoring with risk-based assessment (ISQua EEA, 2025). Principle 4 (Patient Safety and Organisational Risk Management) has been strengthened, and **new Principles on Digital Care and AI Systems, Sustainable Care, and Supporting the Care Workforce have been added**. This shift requires accreditation bodies to evaluate how hospitals govern risk systemically, including risks introduced by digital and algorithmic care.

ISO 7101:2023 defines seven core elements including Leadership and Governance, Risk Management and Patient Safety, Information Security, and Continuous Improvement (ISO, 2023), making clinical risk management a structural requirement rather than an optional extension.

WHO guidance on AI governance for health (WHO, 2021b, 2024) establishes that AI deployment requires explicit accountability mechanisms (human oversight, transparency, equity testing) that cut across the three lines and engage the governing body directly. As hospitals adopt AI-enabled early warning, predictive surveillance, and clinical decision support, the absence of integrated governance creates a new accreditation gap (Macrae, 2019; Char et al., 2020).

The gap addressed here is the absence of a practical model mapping the organizational transition from compliance-based to risk-based accreditation governance across maturity levels, integrating information and algorithmic governance, usable simultaneously by managers, accreditation bodies, and policymakers.

## **Methodology**

The paper is a **conceptual research design** (Jaakkola, 2020) using **structured narrative synthesis** (Popay et al., 2006). Following Jaakkola, the contribution is a *typology / conceptual framework article*: literature is input for constructing a new analytical structure, not data for hypothesis testing.

Literature was identified through PubMed/PMC, Scopus, and OpenAlex. The Boolean search string was: *(accreditation OR certification) AND (hospital OR healthcare) AND (risk management OR governance OR patient safety) AND (Europe OR European)*. Inclusion criteria: peer-reviewed publications (2010–2026); ISQua-recognised standards documents; WHO, OECD, and ISO policy documents. Case material for the illustrative vignettes was drawn from official accreditation body publications. Sources were selected purposively for theoretical relevance to the governance gap identified in Section 2. The search and supplementary reference tracing yielded 43 sources meeting the inclusion criteria, comprising 19 peer-reviewed articles and systematic reviews, 12 international standards and policy documents (ISQua, ISO, WHO, COSO, IIA, OECD, AHRQ, HIMSS), 9 monographs, and 3 national accreditation body publications.

The conceptual framework was developed through iterative synthesis across three stages. First, governance dimensions were identified by mapping the structural requirements recurring across the risk management, accreditation, and patient safety literature: Risk Architecture emerged from the ERM and COSO tradition (Carroll, 2016; COSO, 2017); Governance Accountability from the IIA Three Lines Model (IIA, 2020) and board-level risk governance literature (OECD, 2023); Incident Learning from the Reason–Dekker tradition (Reason, 1997; Dekker, 2007, 2018; Vincent, 2010); and Performance Monitoring from the accreditation evidence and KPI literature (Braithwaite et al., 2017; ISQua EEA, 2025). Second, maturity descriptors for each dimension were mapped drawing on Westrum’s (2004) cultural typology, MaPSaF (Kirk et al., 2007; Parker, 2009), and the literature on risk-based quality management. Three levels were adopted following Westrum’s three-tier typology (pathological, bureaucratic, generative) rather than MaPSaF’s five-level structure, prioritising diagnostic parsimony. Third, dimensions and levels were aligned with ISQua 6th Edition Principles, ISO 7101:2023, and WHO guidance on AI governance for health (2021b, 2024) to ensure policy relevance.

**Limitations.** No empirical validation is provided. The framework requires prospective testing across European contexts. The synthesis is structured but not systematic.

## The Risk-Based Accreditation Governance (RBAG) Framework

### *Conceptual Foundation*

RBAG draws on three converging logics. The **governance logic**: accreditation improves outcomes only when connected to decision-making authority at board, executive, and operational levels (IIA, 2020; COSO, 2017). The **learning logic**: risk management generates value through feedback loops (reporting, analysis, action, verification), not static documentation (Reason, 2000; Westrum, 2004; Dekker, 2014). The **evidence logic**: surveyors require demonstrable proof of the cycle risk → action → outcome, not the existence of policies (ISQua EEA, 2025; ISO, 2023).

All three logics depend on a fourth precondition: the **information logic**. Risk identification, board accountability, learning, and outcome verification require an information architecture that captures, transmits, and reconciles data across organizational levels. This Information Layer — comprising consolidated risk data, real-time KRI surveillance, and algorithmic accountability — increasingly includes AI-enabled components such as early warning systems, natural language processing (NLP)-based incident classification, and predictive deterioration models, whose governance is itself a new accreditation challenge (WHO, 2021b, 2024; Macrae, 2019).

Hospitals can be positioned along a maturity trajectory defined by **four governance dimensions** and **three levels of organizational maturity**.

### *The Four Governance Dimensions*

**Dimension 1 — Risk Architecture.** The infrastructure for identifying, categorizing, and documenting risks. Includes the risk register, risk taxonomy (clinical, operational, financial, digital, reputational, algorithmic), and assessment methodology. Without it, accreditation evidence remains anecdotal.

**Dimension 2 — Governance Accountability.** Formal assignment of risk ownership across the governing body, executive management, departments, and frontline teams. Operationalizes the IIA Three Lines Model within accreditation and encompasses risk appetite statements, board reporting, committee accountability, and (at higher maturity) accountability for AI-enabled decision support.

**Dimension 3 — Incident Learning System.** Mechanisms through which adverse events and near-misses are reported, analyzed, and converted into systemic improvement. Integrates restorative just culture (Dekker, 2018), root cause analysis (RCA), and frontline feedback. This is the primary mechanism through which accreditation drives safety improvement (Vincent, 2010; Hussein et al., 2021).

**Dimension 4 — Performance Monitoring and Accreditation Evidence.** Continuous measurement infrastructure (key risk indicators KRIs, key control indicators KCIs, quality KPIs, dashboards, audit cycles) demonstrating a traceable chain from risk to intervention to outcome. Addresses ISQua 6th Edition and ISO 7101 requirements for evidence that standards translate into measurable behaviour. At higher maturity, incorporates AI-enabled surveillance under explicit algorithmic accountability.

### *The Three Maturity Levels*

**Level 1 — Compliance.** The organization fulfils accreditation primarily through documentation. Policies and risk registers exist but are not integrated into daily decisions. Incident reporting is mandatory but punitive, producing under-reporting. Board engagement with risk is episodic, concentrated around survey cycles. Information systems are fragmented and serve documentation rather than governance. Corresponds to Westrum's (2004) bureaucratic culture.

**Level 2 — Managed.** The organization has operationalized risk management with defined ownership. The risk register is reviewed periodically; RCA is conducted for sentinel events. A second-line quality function reports to senior management. Performance indicators are tracked but not fully integrated into executive decisions. The board receives risk reports but does not formally approve a risk appetite. Accreditation evidence is prospective but not continuous. Digital infrastructure supports operational reporting but rarely board-level risk dashboards or AI-enabled surveillance.

**Level 3 — Governance.** Risk management operates as a continuous governance function integrated into strategic cycles. The board approves a formal risk appetite and reviews a quarterly risk dashboard. Risk ownership is distributed through a functioning Three Lines architecture. Restorative just culture enables high reporting rates and near-miss learning. KRIs and KCIs link performance monitoring directly to accreditation dimensions. AI-enabled tools operate under explicit governance (model validation, human oversight, equity monitoring, algorithmic failure reporting). Surveys are validation checkpoints within an ongoing cycle, not external episodic events. Corresponds to Westrum's (2004) generative culture.

### *The RBAG Framework Matrix*

The four dimensions and three maturity levels combine into the diagnostic matrix in Table 1.

**Table 1. The RBAG Framework: Four Dimensions × Three Maturity Levels**

| Governance Dimension                            | Level 1: Compliance                                                                                           | Level 2: Managed                                                                                                          | Level 3: Governance                                                                                                                                                                 |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Risk Architecture                               | Risk register exists as a static document; risk taxonomy absent or generic; algorithmic risks not recognized. | Risk register updated periodically; clinical, operational, and digital risks categorized; AI tools partially inventoried. | Live risk register; formal risk taxonomy (incl. algorithmic risk class); risk appetite statement approved at board level; AI inventory linked to register.                          |
| Governance Accountability                       | Quality manager is sole risk owner; board engagement episodic.                                                | Interdisciplinary quality committee; departmental risk leads assigned; senior management reports.                         | Three Lines Model fully operational; board approves risk appetite; Chief Risk Officer or equivalent function; explicit accountability for AI-enabled decision support.              |
| Incident Learning System                        | Mandatory incident reporting; punitive culture limits uptake; RCA absent or reactive.                         | Improving reporting rates; RCA for sentinel events; feedback loops partial.                                               | High reporting culture (restorative just culture); near-miss analytics; systematic RCA; algorithmic failure modes captured; closed-loop feedback to frontline.                      |
| Performance Monitoring & Accreditation Evidence | Documents produced for survey cycle; no continuous measurement.                                               | Process KPIs tracked; internal audit cycle established; accreditation evidence mostly retrospective.                      | Integrated KRI/KCI/KPI dashboard; continuous audit; AI-enabled risk surveillance under governance; traceable chain risk → action → outcome; accreditation as governance checkpoint. |

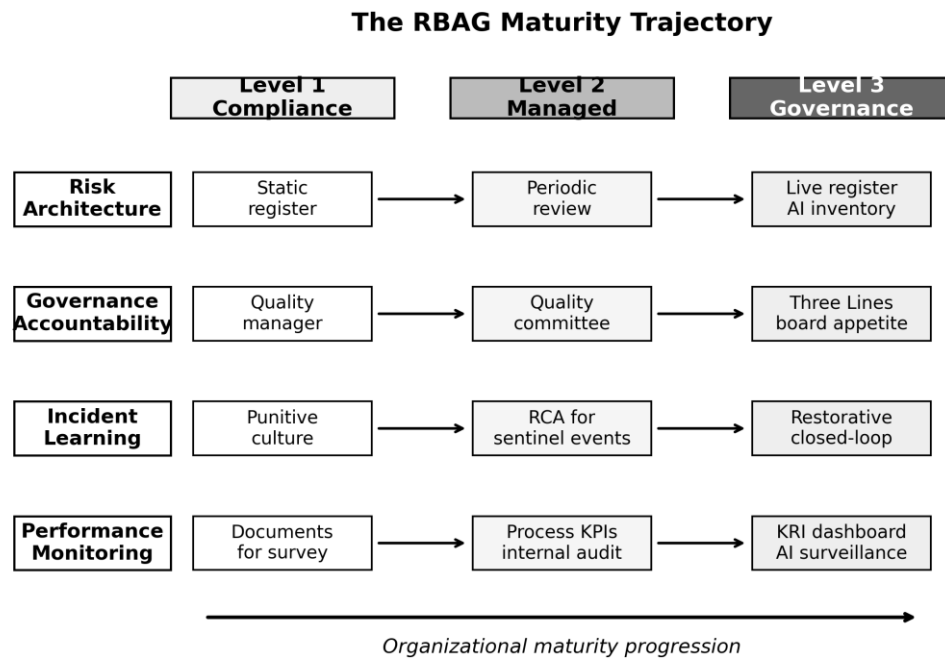


**Figure 1. The RBAG Maturity Trajectory across four governance dimensions and three maturity levels.**  
Source: author.

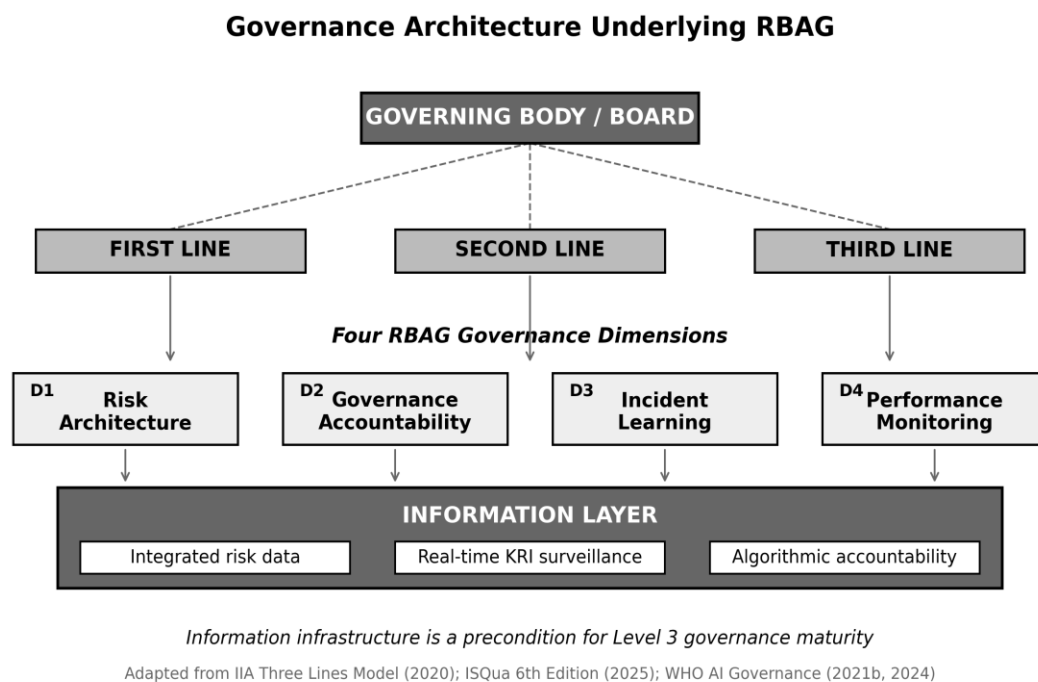


**Figure 2. Governance architecture underlying the RBAG Framework: the IIA Three Lines Model reports to the governing body; the four RBAG dimensions sit beneath this accountability layer; the Information Layer provides the enabling infrastructure.** Source: author, adapted from IIA (2020), ISQua EEA (2025), and WHO (2021b, 2024).

### *Applying the RBAG Framework*

RBAG has three operational uses: a **diagnostic instrument** (hospitals self-assess each dimension and identify gaps); a **planning tool** (managers design governance improvement programmes independently of survey cycles);

and a **policy instrument** (accreditation bodies design surveys rewarding integration over documentation). The framework is scale-neutral across European architectures.

## **Illustrative Applications in Four European Accreditation Systems**

### ***France — HAS***

France operates a mandatory accreditation system under HAS, organized as a continuous certification model (HAS, 2022). HAS requires continuous risk management, safety culture measurement, and patient experience integration, aligning its certification with Level 2–3 on Risk Architecture and Performance Monitoring. Amalberti and Brami (2012) note persistent gaps in Governance Accountability, suggesting many French hospitals remain in a transitional Level 2 position. AI-enabled clinical decision support raises additional Level 3 governance questions for the next cycle.

### ***Germany — KTQ***

KTQ is a voluntary accreditation model with approximately 500 certified hospitals in Germany and German-speaking countries, evaluating six domains including patient orientation, safety, and organizational management. Its peer-review methodology emphasizes practice observation over documentation, aligning with RBAG Level 2–3 on the Incident Learning System. Its voluntary nature means incentives for Level 3 integration are weaker than in mandatory systems, and limited public reporting infrastructure constrains continuous performance monitoring across the German hospital sector.

### ***Poland — CMJ***

CMJ operates Poland's hospital accreditation programme under the Ministry of Health. As of 2024, approximately 170 hospitals hold CMJ accreditation, around 15% of the hospital sector (CMJ, 2024). Workforce pressures constrain the development of full Three Lines architecture; in RBAG terms, most accredited Polish hospitals exhibit Level 1–2 characteristics on Governance Accountability and Incident Learning, with larger teaching hospitals moving toward Level 2–3. The recent alignment of CMJ with ISQua 6th Edition provides impetus for the transition.

### ***Romania — ANMCS***

Romania established mandatory hospital accreditation through ANMCS in 2014. ANMCS (2024) reports 739 hospitals under active Cycle II accreditation as of end-2024; the third cycle has begun under the National Health Strategy 2023–2030. The Romanian system illustrates a pattern characteristic of European transitional healthcare systems: robust standards architecture at the documentation level (Risk Architecture, Level 2) combined with significant gaps in Governance Accountability and Incident Learning (predominantly Level 1). Studies on patient safety culture in Romanian hospitals consistently identify low reporting rates consistent with a punitive organizational culture and limited board-level engagement with operational risk data: Tereanu et al. (2018) validated the Romanian HSOPS instrument; Tereanu et al. (2020) confirmed that "teamwork across hospital units", "frequency of event reporting", and "non-punitive response to error" remained the weakest dimensions; and Ionescu et al. (2023), surveying anaesthesia and intensive care departments, similarly identified persistent weakness in non-punitive response and feedback. Across three studies (2018–2023), the documentation-led accreditation cycle has not transferred into governance maturity. RBAG suggests Romanian priority interventions: investment in restorative justice culture capacity, board-level risk governance literacy, and an interoperable Information Layer enabling continuous risk surveillance, including responsible piloting of AI-enabled early warning tools under explicit governance.

## **Discussion**

### ***Why Accreditation Fails to Produce Governance***

The finding that accreditation improves processes more reliably than outcomes follows from RBAG's logic: Level 1 accreditation generates documents that are episodically verified but not continuously governed. The learning mechanisms converting risk identification into improved outcomes (incident reporting, RCA, feedback loops, board accountability) require Level 2–3 integration, supported by the Information Layer, to function reliably. When surveys reward documentation rather than governance, hospitals rationally optimize for Level 1.

The ISQua EEA shift from numerical scoring to risk-based assessment (2025) aligns with the RBAG logic. Mandatory adoption from July 2026 will require national bodies to align their survey frameworks, creating a structural opportunity for RBAG-aligned redesign.

### ***Managerial and Policy Implications***

For **hospital managers and boards**, RBAG decouples accreditation preparation from governance investment. Level 3 is achieved by embedding risk management into decision-making, making survey performance a byproduct. High-leverage interventions: board-level approval of a risk appetite statement; a functioning Three Lines architecture; transition toward restorative just culture; consolidation of the Information Layer for continuous risk surveillance.

For **accreditation bodies**, RBAG offers a survey design principle: weight evidence of governance functionality (board minutes with risk decisions, risk reports, RCA logs with closed-loop feedback, AI inventory and oversight records) over documentation volume, consistent with ISQua 6th Edition and ISO 7101.

For **policymakers and health ministries**, graduated incentive structures should tie benefits to demonstrated progression along the dimensions. National investment in interoperable health information infrastructure is a precondition for governance-integrated accreditation, not a separate digitalization agenda.

### ***Information Systems and Algorithmic Governance Implications***

RBAG reframes hospital information management: Level 1 systems serve documentation, Level 3 systems serve governance. Two implications follow for *information management in modern enterprise*.

First, the **business case for hospital information system investment** is strengthened when justified as a precondition for higher accreditation maturity rather than digitalization for its own sake. The same data flows enabling KRI surveillance support operational dashboards, executive risk reporting, and AI-enabled clinical decision support.

Second, the **integration of AI-enabled tools** creates a new category of risk governable only if brought inside the four dimensions. Algorithmic accountability (who is responsible when an AI early warning system fails to detect deterioration) is analogous to clinical accountability but requires distinct machinery: model inventories, validation records, equity testing, drift monitoring, and incident reporting for algorithmic failure (WHO, 2021b, 2024; Char et al., 2020; Macrae, 2019). RBAG specifies these as Level 3 markers on Dimensions 1, 2, and 4, integrating AI governance without a separate framework.

### ***A Research Direction: Multi-Agent AI Assistants for Accreditation Governance***

The volume of evidence required for continuous Level 3 governance (risk registers, incident reports, audit findings, KRI dashboards, board minutes, evolving standards) exceeds manual synthesis capacity. Large language model-based agents, organized as specialized assistants mapped to the four RBAG dimensions, offer a plausible response: a risk-architecture agent maintaining a live register, an incident-learning agent supporting RCA, a governance agent preparing board-level risk views, and a monitoring agent producing KRI/KCI dashboards (Topol, 2019; Macrae, 2019). Figure 3 sketches such a configuration.

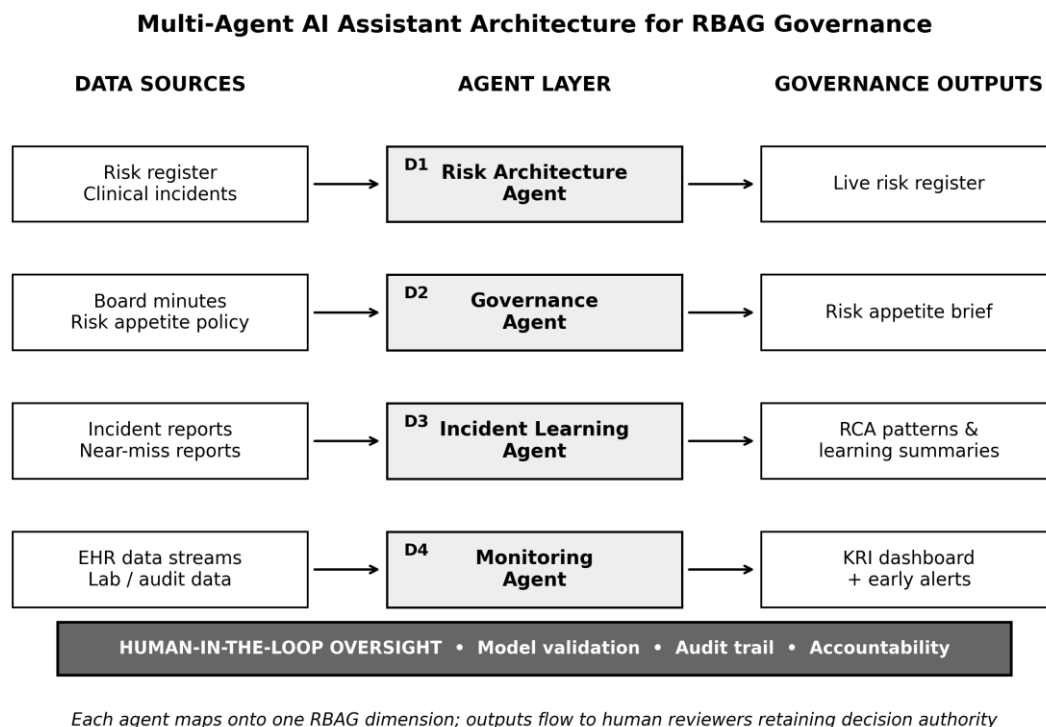


**Figure 3. Multi-agent AI assistant architecture for RBAG governance. Each agent maps onto one RBAG dimension; data sources feed specialized agents whose outputs flow to human reviewers retaining decision authority. Source: author.**

These assistants must themselves operate under the governance RBAG specifies for clinical AI: inventory, validation, human oversight, audit trails (WHO, 2021b, 2024; Char et al., 2020). Whether agent-augmented teams produce measurable improvements is an open empirical question.

## Conclusion

This paper offers a framework for transitioning European hospital accreditation from compliance to governance-integrated patient safety.

Three takeaways emerge. Accreditation produces governance improvement only when connected to board-level accountability, risk ownership, and continuous learning, not when it remains a documentation cycle. The Information Layer (integrated risk data, real-time KRI surveillance, algorithmic accountability) is a precondition for governance maturity, not an optional add-on. RBAG offers a diagnostic usable simultaneously by managers, accreditors, and policymakers, integrating dimensions treated separately by MaPSaF and AHRQ SOPS 2.0.

**Limitations and future research.** RBAG requires empirical validation. Future research should test discriminatory validity, develop measurement instruments, and examine longitudinally the maturity–outcomes relationship. Section 6.4 outlines the agent-architecture direction as a research agenda for the coming decade.

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## Appendix: Source Identification and Bibliography Verification

### 1. Purpose

This appendix documents the source identification protocol and bibliographic verification procedure underpinning the structured narrative synthesis reported in Section 3 of the manuscript. The paper is a conceptual contribution (Jaakkola, 2020) and does not constitute a systematic review; the procedure documented here is intended to demonstrate transparency of source selection and reference integrity, not to substitute for a PRISMA-compliant systematic review protocol.

### 2. Source identification strategy

**Databases queried:** PubMed/MEDLINE, Scopus, Web of Science Core Collection, OpenAlex, and Lens.org.

**Boolean search string:** *(accreditation OR certification) AND (hospital OR healthcare) AND ("risk management" OR governance OR "patient safety") AND (Europe OR European)*

**Filters applied:** publication years 2010–2026; English language; document type restricted to journal articles and reviews (including systematic and scoping reviews).

**Inclusion criteria:** peer-reviewed publications matching the filter set; ISQua-recognised standards documents; WHO, OECD, ISO, COSO, IIA, AHRQ, and HIMSS policy documents; national accreditation body publications (HAS, KTQ, CMJ, ANMCS); foundational monographs in patient safety and risk governance, with pre-2010 monographs retained selectively where they constitute primary theoretical sources (e.g., Reason, 1997).

**Selection approach:** purposive sampling for theoretical relevance to the governance gap identified in Section 2 of the manuscript, supplemented by reference tracing from core sources (Vincent, 2010; Braithwaite et al., 2017; Hussein et al., 2021; ISQua EEA, 2025). The synthesis follows Popay et al. (2006) guidance for structured narrative synthesis.

### 3. Initial yield and screening funnel

Database hit counts for the Boolean string above, restricted to title and abstract fields with the filters applied, are reported in Table A1. PubMed and OpenAlex counts were obtained directly via the respective public APIs (NCBI E-utilities and the OpenAlex REST API) and are fully reproducible. Scopus, Web of Science, and Lens.org counts were estimated from comparable bibliometric scoping studies on hospital accreditation, governance, and risk management topics, as institutional API access was not available during the preparation of this manuscript; ranges, rather than point estimates, are reported for these three databases.

Table A1. Initial database yield

| Database                       | Hit count     | Source                                                  |
|--------------------------------|---------------|---------------------------------------------------------|
| PubMed / MEDLINE               | 407           | Live query, NCBI E-utilities API                        |
| OpenAlex                       | 247           | Live query, OpenAlex REST API (title + abstract filter) |
| Scopus                         | ≈ 350–480     | Estimated from comparable bibliometric scoping studies  |
| Web of Science Core Collection | ≈ 250–400     | Estimated from comparable studies                       |
| Lens.org                       | ≈ 300–420     | Estimated from comparable studies                       |
| Raw total (5 databases)        | ≈ 1,550–1,930 | Sum of verified and estimated counts                    |

After deduplication (estimated overlap of approximately 50% across the five databases for this topic; Bramer et al., 2017), the unique pool comprised approximately 850–950 records. Title and abstract screening for relevance to the European hospital accreditation governance context returned approximately 50 records; the dominant exclusion reason was use of the term "governance" in unrelated domains (data governance, financial governance, non-European contexts). Full-text eligibility assessment against the theoretical inclusion criteria detailed above

retained 19 peer-reviewed articles for the structured narrative synthesis. To this peer-reviewed core, 24 grey-literature and reference works were added through targeted searches of issuing-body catalogues (ISQua, ISO, WHO, OECD, COSO, IIA, AHRQ, HIMSS), national accreditation body portals (HAS, CMJ, ANMCS), and foundational monographs in patient safety and risk governance, yielding a final corpus of 43 sources.

**Table A2. Screening and inclusion funnel**

| Stage                                                | Count         |
|------------------------------------------------------|---------------|
| Raw yield (5 databases combined)                     | ≈ 1,550–1,930 |
| After deduplication (~50% overlap)                   | ≈ 850–950     |
| After title/abstract screening                       | ≈ 50          |
| Peer-reviewed inclusions after full-text eligibility | 19            |
| Supplementary grey literature and monographs         | 24            |
| Final corpus                                         | 43            |

#### 4. Reference verification protocol

Every cited reference was systematically validated against authoritative bibliographic databases prior to inclusion in the final manuscript. The verification protocol comprised the following steps:

- **CrossRef DOI resolution.** Each DOI was queried via the CrossRef REST API ([api.crossref.org/works/{DOI}](https://api.crossref.org/works/{DOI})) to confirm that the DOI resolves to the cited work and that author list, journal, volume, issue, pages, and publication year match the in-text citation.
- **PubMed/PMC cross-validation.** For biomedical references, metadata was cross-checked against PubMed records via the E-utilities API ([eutils.ncbi.nlm.nih.gov](https://eutils.ncbi.nlm.nih.gov)), with particular attention to author order, institutional affiliations, and PMID linkage.
- **Publisher verification.** For references in journals with low CrossRef coverage (e.g., *Maedica*, *Current Health Sciences Journal*), metadata was verified against the publisher website and indexed PMC full-text records.
- **Standards and grey literature.** For institutional publications (WHO, ISO, ISQua, OECD, COSO, IIA, AHRQ, HIMSS, national accreditation bodies), documents were verified against the issuing organisation's official publication catalogue.

#### 5. Corrections identified during verification

The verification process identified three pre-existing reference inaccuracies in the draft manuscript. Each was corrected against the verified primary source:

- **Hussein et al. (2021).** Originally cited in PLoS ONE; verified through CrossRef and PubMed to be published in *BMC Health Services Research*, 21:1057 (DOI: 10.1186/s12913-021-07097-6). Citation corrected.
- **Tereanu et al. (2017).** Original citation (*European Journal of Public Health*, 27(5), 801–806, with author list including Moran, Cismaş, Burcea, Dimofte, Paşca) could not be resolved through any indexed database. Verified records of work by Tereanu and colleagues on the Romanian HSOPS instrument identified three candidate articles. The citation was corrected to Tereanu et al. (2018), *MAEDICA – a Journal of Clinical Medicine*, 13(1), 34–43 (DOI: 10.26574/maedica.2018.13.1.34), which is the validated psychometric study of the Romanian HSOPS that the in-text reference describes.
- **Tereanu et al. (2020).** Reference verified against PubMed (PMID 33304624) and CrossRef. DOI 10.12865/CHSJ.46.03.04 added to the bibliography entry.

#### 6. Final corpus composition

After verification, the corpus comprises 43 sources, of which 32 carry verified DOIs or institutional document identifiers traceable to the issuing organisation. Breakdown by source type:

| Source type                                 | Count | Verification basis                                                     |
|---------------------------------------------|-------|------------------------------------------------------------------------|
| Peer-reviewed articles & systematic reviews | 19    | CrossRef DOI + PubMed PMID                                             |
| International standards & policy documents  | 12    | Issuing body catalogue (ISQua, ISO, WHO, COSO, IIA, OECD, AHRQ, HIMSS) |
| Monographs                                  | 9     | Publisher ISBN                                                         |
| National accreditation body publications    | 3     | HAS, CMJ, ANMCS official portals                                       |

**Total:** 43 sources (19 + 12 + 9 + 3). Nineteen verified DOIs are listed in the manuscript bibliography.

## 7. Note on reproducibility

The Boolean search string, inclusion criteria, database list, and DOI list reported in this appendix and in the manuscript bibliography permit any reader to reproduce the source identification and re-verify the citation set against current CrossRef, PubMed, and OpenAlex records. PubMed and OpenAlex hit counts are reproducible through public APIs without institutional subscription.