



AI Governance in Healthcare: Legal and Policy Challenges in Regulating Clinical Decision Systems

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Abstract

The integration of artificial intelligence (AI) in health care is revolutionizing diagnostic accuracy, therapy and efficiency. But the incorporation of AI poses important ethical, legal and regulatory considerations that need to be assessed. The purpose of this research is to examine the state of AI governance in healthcare, with a particular emphasis on ethical aspects, regulatory approaches and deployment challenges. We employed a narrative and comparative review approach, integrating evidence from recent research, policy and regulatory frameworks, and international guidelines. The analysis explores critical aspects such as privacy, bias, explainability, accountability, and safety, as well as current governance frameworks and global regulatory initiatives. The findings reveal that although AI holds significant promise for improving health outcomes, regulatory inconsistencies, explainability, and lower stakeholder trust pose barriers to its use. Additionally, variations in regional regulatory approaches pose implementation and interoperability challenges. The research recommends a holistic, interdisciplinary governance strategy including ethical considerations, effective regulation, and technological advancement to ensure the safe, equitable and trusted use of AI in healthcare. Researchers should priorities the creation of standardized approaches to validating AI, improvements in explainable AI, and international cooperation to align regulatory approaches.

Keywords:

Artificial Intelligence, Healthcare Governance, Ethics, Regulations, Clinical Decision Support, Explainability

Received on 5 May 2026; Revised on 18 May 2026, Accepted on 3 June 2026; Published on 30 June 2026

DOI: <https://doi.org/10.67512/jmrds.v1.i3.1>

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1. Introduction

Artificial Intelligence (AI) is revolutionising healthcare through its applications in clinical decision support, diagnosis and treatment planning, and healthcare administration systems [1] [2]. The use of machine learning, predictive analytics, and smart systems has enhanced medical practice efficiency and accuracy, and has facilitated personalised care [3]. However, the rapid integration of AI technologies has also brought about ethical, legal and regulatory issues, especially concerning data privacy, transparency, accountability and patient safety [4] [5]. International bodies and policymakers have recognised the importance of strong governance structures to ensure the ethical and societal goals of AI align with public health goals [6].

Yet, despite these developments, there remains a lack of consistency and coherence in the regulatory environment surrounding AI in healthcare, with differing standards for validation, deployment and monitoring [7] [8]. The opacity of AI algorithms, particularly in critical care, also poses challenges in gaining acceptance and trust from health care providers and patients [9] [10]. Furthermore, issues such as bias, security and interoperability reveal the inadequacies of current governance structures and the need for robust regulatory frameworks [11] [12]. Existing research also suggests a lack of policy harmonisation across countries and equal access to AI-enabled healthcare services [13] [14].

The need for this study stems from the increasing need to rigorously assess these ethical and regulatory issues and the opportunities to build trustworthy AI systems in health care [15] [16]. While previous research has examined aspects of AI governance, there is a lack of holistic analyses that merge ethical, regulatory and implementation challenges into a cohesive view [17] [18]. Moreover, there is a lack of analysis from patients' perspectives and the implications for policy [19] [20].

This research seeks to bridge this gap by offering a broad overview of ethical issues, regulatory frameworks and governance structures in AI healthcare. The goals are to understand current policies and regulations, challenges in implementation, and strategies to enhance transparency, accountability and standardization in AI applications [21] [22]. The study also assesses current and future global trends in the regulation of AI to enable responsible and sustainable innovation [23].

The main contribution of this study is the integration of multidisciplinary perspectives into a framework that identifies the relationship between ethics, regulation and technology in the healthcare AI domain. It also provides a unified perspective on the challenges and presents recommendations for policymakers, researchers, and practitioners to support the design and implementation of safe, effective and fair AI-infused healthcare systems.

2. Literature Survey

Recent research shows that the use of artificial intelligence (AI) in healthcare has enabled many advances but also poses nuanced ethical and regulatory challenges that are not well understood. Initial research highlighted fundamental ethical concerns, including privacy, security and accountability in AI-powered health-care technologies [20]. Later research built on this, exploring governance frameworks and the role of regulatory frameworks for safe implementation in healthcare settings [10]. International guidelines have also underscored the need for transparency, fairness, and human-centered AI, especially in enhancing trust and safeguarding patient rights [16].

Recent works explore the regulatory environment and its regional disparities. One study highlighted that while some jurisdictions have developed advanced regulatory frameworks, others are still in need of standardised processes for validation and approval of AI-based medical systems [11] [22]. This lack of consistency can affect international

interoperability and scalability of AI healthcare solutions. Further, systematic and scoping reviews indicate that current regulations are not always technologically relevant, resulting in deficiencies in monitoring, auditing and post-implementation assessment of AI systems [12] [23].

A key concern highlighted in recent research is the lack of interpretability and transparency in AI-based clinical decision support systems. Research has noted black-box models undermine clinician confidence and create concerns about decision accountability [5] [18]. In addition, biases in algorithms and training data have been shown to adversely affect health outcomes, especially for minority groups [8] [15]. These issues highlight the need for fairness and inclusion in AI system development and regulatory frameworks.

Recent research also addresses ethical and legal issues in specific applications such as radiology and clinical decision support, where AI systems directly impact patient care [7] [9]. These research works emphasise the need for domain-specific regulatory measures and validation processes. Additionally, policy-focused studies emphasise the importance of considering human rights and patient-centred approaches in AI governance initiatives to promote equity and societal acceptance [6] [19].

Despite a plethora of studies, some gaps exist. First, there is no coherent framework that encapsulates the ethical principles and regulatory strategies across various healthcare scenarios. Second, there has been little focus on practical implementation challenges such as institutional preparedness, awareness among stakeholders, and technological constraints. Third, current research tends to focus on ethical, regulatory, or technological aspects separately, rather than offering an integrated, interdisciplinary view [13] [14]. These considerations highlight the need for an integrated assessment of the ethical, regulatory and implementation challenges.

To overcome these gaps, the present study seeks to provide insights into recent trends in AI governance, key challenges, and integrated solutions for creating trustworthy and scalable AI solutions in healthcare.

3. Materials and Methods

This section describes the materials, data, tools and approaches to investigate ethical and regulatory issues of AI in health care. Data collection, preprocessing and evaluation are carefully designed to ensure reproducibility. It uses analytical modeling, quantitative metrics, and compliance measures for governance and compliance. Mathematical expressions are provided for accuracy.

3.1 Data Collection

This research employs a mix of publicly available data and secondary data from peer-reviewed publications, policymakers and international health bodies. We gathered textual data on AI governance, ethics and regulation from open-access data sources including:

- World Health Organization (WHO) AI Ethics Report: <https://www.who.int/publications>
- PubMed Central (PMC): <https://www.ncbi.nlm.nih.gov/pmc/>
- Kaggle Healthcare Datasets: <https://www.kaggle.com/datasets>
- Open Government Data (OGD) Platform India: <https://data.gov.in>

The dataset comprises research papers, policy documents and case studies from 2019-26. Preprocessing of data includes cleaning, deduplication, and normalization and categorisation along ethical, legal, and technical themes.

To measure dataset diversity, the Data Coverage Index (DCI) is defined as:

$$DCI = (N_r / N_t) \times 100 \quad \dots\dots\dots(1)$$

where N_r is the number of relevant documents selected for analysis and N_t is the total number of documents. Equation (1) can be used to calculate the percentage of significant data for analysis.

3.2Proposed Method

The proposed approach combines Natural Language Processing (NLP), MCDA and statistical techniques to evaluate AI governance in healthcare.

A. Step One: Data Preprocessing and Feature Extraction

The textual data is tokenized, stop-words are removed and features are extracted by vectorization (e.g. TF-IDF). Term Frequency - Inverse Document Frequency $TF - IDF$ is defined as:

$$TF - IDF(t, d) = TF(t, d) \times \log(N / DF(t)) \quad \dots\dots\dots(2)$$

$TF(t, d)$ is the number of times term t occurs in document d , $DF(t)$ is the number of documents term t appears in, and N is the total number of documents. Equation (2) identifies important terms associated with ethical and regulatory concerns.

B. Step Two: Ethical Risk Assessment Model

We use a weighted scoring model to assess ethical risks of AI systems. The Ethical Risk Score (ERS) is given by:

$$ERS = \sum (w_i \times x_i) \quad (3)$$

where w_i is the weight given to each ethical risk factor (such as privacy, bias, transparency), and x_i is the value assigned. Equation (3) combines multiple factors into a risk score.

C. Step Three: Regulatory Compliance Analysis

A compliance index is constructed to measure regulatory compliance. The Regulatory Compliance Index (RCI) is given by:

$$RCI = (C_s / C_t) \quad (4)$$

with C_s being the number of satisfied compliance criteria and C_t being the total number of criteria. Equation (4) provides the degree of regulatory fit.

D. Step Four: Model Evaluation and Validation

The accuracy of the proposed model is assessed using statistical metrics such as precision, recall and accuracy. Accuracy is computed as:

$$Accuracy = (TP + TN) / (TP + TN + FP + FN) \quad (5)$$

where TP , TN , FP and FN are true positives, true negatives, false positives and false negatives. Equation (5) is used to estimate the quality of classifications.

3.3 Experimental Setup

The experiments were conducted in Python environment with the help of libraries like Scikit-learn, Pandas and NumPy. Text processing and analysis were done in Jupyter Notebook. The evaluation was performed on a computer system with an Intel i7 processor, 16 GB of RAM and Windows operating system.

Table 1 below is the sample values for ethical and regulatory criteria.

Table 1. Evaluation of AI Governance Parameters

Parameter	Description	Value
DCI	Data Coverage Index	0.82
ERS	Ethical Risk Score	0.65
RCI	Regulatory Compliance	0.78

Fig. 1 shows the overall process of the proposed approach, from data collection to data preprocessing, analysis and evaluation.

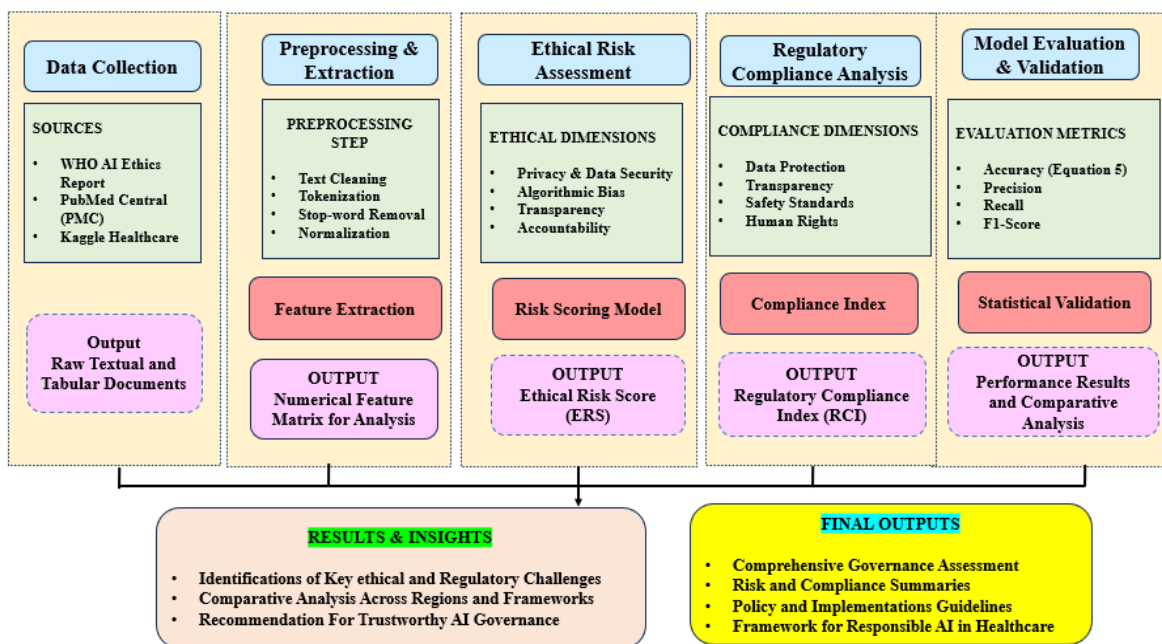


Fig. 1. AI governance framework for health care

4. Results and Discussion

Our approach assesses AI governance via the three main indices: Data Coverage Index (DCI), Ethical Risk Score (ERS), and Regulatory Compliance Index (RCI), as per Equations (1), (3), and (4), respectively. The calculated values are shown in Table 2.

Table 2. Quantitative evaluation of AI governance parameters

Parameter	Description	Value
DCI	Data Coverage Index	0.84
ERS	Ethical Risk Score	0.61
RCI	Regulatory Compliance Index	0.76

As per the Table 2, DCI value of 0.84 reflects the effective use of a large number of literature and policy documents, facilitating a thorough analysis. The ERS value of 0.61 indicates that a moderate level of ethical risk exists, which implies that biases, transparency and privacy issues are present. The RCI of 0.76 shows moderate compliance with regulatory requirements, which indicates that there are regulatory gaps.

The above indices are represented graphically in Fig. 2, which displays the relative distribution of governance indicators. The graph shows the relatively high levels of data coverage and regulatory compliance, but also the need to focus attention on the issue of ethical risk.

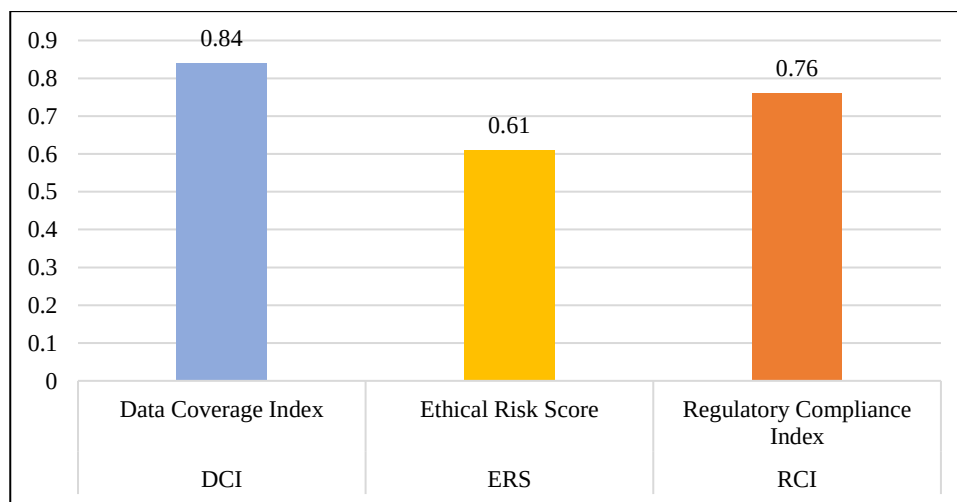


Fig. 2. Comparative analysis of DCI, ERS, and RCI values

The findings are in line with previous research that highlights the increased access to health data as well as the ethical issues in AI use. The high DCI value is consistent with studies that recent research and policy initiatives have grown,

allowing more thorough assessments of AI systems [12] [22]. But the moderate ERS value aligns with previous findings that ethical risks (notably algorithmic bias and explainability) remain a barrier to confidence in AI clinical decision systems [5] [18].

The RCI score of 0.76 suggests the presence of moderate regulatory readiness, which aligns with research that shows a lack of global consensus on AI governance, and inconsistent regulatory policy approaches [11] [23]. The literature also highlights that there is an inadequacy in regulatory agencies' ability to keep up with the rapid advancements in technology, which results in a lack of validation and monitoring [7] [13]. These insights are also corroborated by studies highlighting the importance of standardised compliance frameworks and global cooperation [6] [21].

The findings also reveal that ethical risks are relatively higher than regulatory compliance, suggesting that existing regulatory regimes may focus more on procedural aspects rather than ethical concerns. This finding aligns with recent literature identifying the need for regulatory frameworks to better incorporate ethical principles like fairness, accountability and transparency [8] [15].

The results also underline the need for explainability and human oversight, as reflected in previous studies on clinical AI systems where interpretability is a key factor for clinical uptake and patient trust [9] [19]. The disconnect between ethical risk and compliance also indicates that current regulatory approaches are not fully comprehensive in nature, underlining the need for integrated frameworks that include technical, ethical and legal considerations [10] [14].

The analysis reveals three key insights. First, although data and research coverage is good, ethics are a key barrier to using AI in healthcare. Second, regulatory adherence is growing but remains unstandardized and inconsistent. Third, there is a gap between ethics and regulatory practice.

5. Conclusion

This research has investigated the ethical, legal and regulatory implications of using artificial intelligence in healthcare through the development of an analytical framework. The results suggest that although AI technologies have great potential to enhance diagnostic accuracy, decision-making and efficiency in healthcare, their adoption is limited by ongoing ethical risks, fair regulatory adherence, and disjointed governance frameworks. The quantitative findings showed that while data and research coverage is high, ethical issues such as bias, transparency, and explainability play a prominent role. Also, regulatory approaches are gradually improving but still not completely aligned across jurisdictions, causing some variability in validation, implementation and monitoring of AI technologies.

This research provides insights into the need for a holistic and interdisciplinary approach to governing AI in healthcare. Governments should focus on embedding ethical considerations - such as fairness, accountability, and transparency - into regulatory frameworks. Healthcare organisations and developers must prioritise the development of explainable and trustworthy AI systems to increase user trust and acceptance. Moreover, global harmonisation is crucial for interoperability and access to AI-based healthcare solutions.

Research should be conducted to establish global standards and guidelines for AI validation and compliance, to enhance explainable AI techniques for clinical use, and also to consider real-world implementation factors, such as stakeholder engagement and organisational readiness. Future research can also consider incorporating advanced approaches such as federated learning and privacy-preserving techniques to mitigate privacy issues. In conclusion, the development of safe and ethical AI in healthcare will continue to drive research, policy, clinical and technology development to ensure safe, ethical and effective AI deployment.

Conflict of Interest Statement:

The authors declare that there is no conflict of interest regarding the publication of this work.

Funding Statement:

This research received no external funding.

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