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Assessing the Readiness of European Healthcare Institutions for EU AI Act Compliance

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Abstract. The European Union's Artificial Intelligence Act (EU AI Act) proposes a comprehensive regulatory framework for Artificial Intelligence (AI), emphasizing transparency, accountability, and ethical considerations, particularly in high-risk sectors like healthcare. This study assesses the readiness of European healthcare institutions for compliance with the EU AI Act. Using a systematic analysis of news articles and publications, we examine the current discourse on AI governance, compliance challenges, and implementation strategies within the European healthcare context. Our study findings indicate a big gap between AI adoption and compliance preparedness; hence, healthcare institutions should have increased awareness and strategic planning.

Keywords. EU AI Act, healthcare institutions, compliance, artificial intelligence

1. Introduction

Artificial intelligence forms the core in transforming the whole health sector, encompassing areas, ranging from diagnosis to treatment strategies, management of patients, and operational productivity. Developments in machine learning, data analytics, and initiatives toward digital transformation raise great impetus in the adoption of AI technologies in the field of healthcare across the European continent. However, the

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integration of AI frameworks introduces both significant challenges and critical issues related to data confidentiality, biased algorithms, ethical consequences, and patient safety. To address these concerns, the European Union has responded by adopting the AI Act [1]. This act classifies the AI systems based on risk, often placing healthcare applications into the high-risk category since much of the applications involve high stakes regarding human life and well-being. Consequently, this dictates that the health care institutions should be ready to comply with the requirements of the EU AI Act regarding data governance, transparency, human oversight, and risk management. However, the whole community has not yet attained the necessary maturity to effectively integrate high risk AI systems into everyday life as the requirements are very high [2]. The present discourse is evaluated as a method for assessing the preparedness of European healthcare institutions towards compliance with the EU AI Act and determining the necessary points of focus.

2. Materials and Methods

2.1. Data Collection

Our approach involves collecting data through the NewsAPI, a news aggregator service that provides access to recent articles from various sources. We employed a comprehensive list of keywords related to AI adoption, governance, compliance, and readiness in European healthcare institutions. We queried the NewsAPI for articles published between September 22, 2024, and October 21, 2024. The searches were conducted in English and limited to peer-reviewed journals, trade publications, and reputable news sources.

2.2. Data Analysis

For our data analysis we retrieved 988 unique articles related to the keywords. The articles were processed using text mining techniques to extract relevant information. Subsequently, we analyzed the frequency of keywords to identify the most discussed topics.

2.3. Visualization

We implemented two basic visualization techniques:

Radar (Spider) Chart: The quantity of discourse related to the top 10 keywords is represented in a radar chart, whereby it is easier to determine where discourse has increased and where it has diminished.

Word Cloud: This has been developed by thoughtfully using a selection of keywords and relevant article titles that together serve to represent the importance of the various topics in the compiled dataset.

The visualizations were produced using Python's libraries, matplotlib and wordcloud.

3. Results

3.1. Keyword Frequency Analysis

The analysis revealed that "AI European Healthcare" was the most frequent keyword, appearing in 100 articles, followed by "AI Governance Healthcare" which was found in 85 articles, and "Digital Transformation Healthcare Europe" appearing in 84 articles. However, keywords directly related to compliance readiness, such as "AI Regulatory Readiness Healthcare," appeared less frequently, indicating potential gaps in focus (see Table 1).

Table 1. Top 10 keywords by article count.

Keyword	Article Count
AI European Healthcare	100
AI Governance Healthcare	85
Digital Transformation Healthcare Europe	84
Human Oversight AI Systems	82
Artificial Intelligence Regulation Europe	78
Healthcare AI Readiness	61
Healthcare AI Patient Safety	60
AI Compliance Healthcare	55
AI Transparency Healthcare	43
AI Risk Management Healthcare	39

3.2. Radar Chart Visualization

The Radar Chart (Figure 1) illustrates the comparative article counts for the top 10 keywords. The chart highlights that while general AI topics attract substantial attention, specific areas related to compliance and regulatory readiness are less discussed.

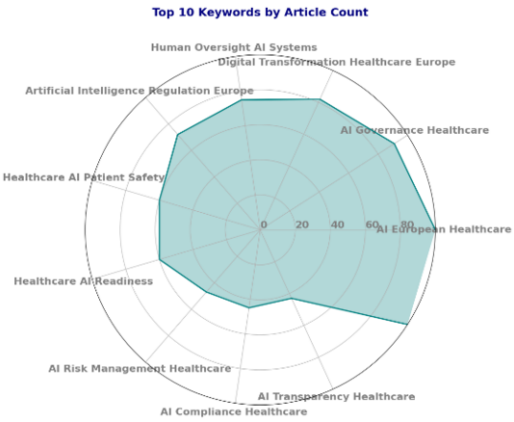

Figure 1. Radar Chart depicting the number of articles per top 10 keywords.

3.3. Word Cloud Visualization

The Word Cloud visualization (Figure 2) presents the prominence of various topics based on keyword frequency. Larger words represent higher frequency, emphasizing the dominance of general AI topics over compliance-specific ones.

Figure 2. Word Cloud visualization of keywords from the collected articles

4. Discussion

The findings indicate a very good awareness of and interest in the use of artificial intelligence in European healthcare. On the other hand, there is a big gap between general talks on artificial intelligence and focused priority for preparedness towards compliance with the EU AI Act [3]. Conversations centered on "AI Regulatory Readiness in Healthcare" and "AI Compliance Frameworks in Healthcare" were the least discussed; thus, compliance does not seem to take center stage in present conversations. This disparity between awareness and action suggests that, while healthcare stakeholders are captivated by AI's transformative potential, the nuances of regulatory adherence are yet to become a mainstream concern. Compliance with the EU AI Act demands a robust understanding of risk categorization, data protection, and algorithmic transparency, which many institutions may view as secondary to immediate operational improvements AI can provide [7].

Moreover, the discussions around "AI Regulatory Readiness" and "AI Compliance Frameworks" indicate an ongoing disconnect, possibly due to the perceived complexity and resource demands that these regulatory requirements entail. Healthcare institutions may prioritize innovation and AI-driven advancements that can directly enhance patient outcomes and operational efficiency, while compliance considerations might be perceived as a secondary, albeit necessary, stage in the adoption process. Without a focused approach to regulatory preparedness, healthcare institutions may face obstacles in aligning their AI initiatives with compliance expectations, posing risks to patient trust, legal standing, and long-term AI integration. To bridge this gap, institutions must foster a compliance-focused culture alongside their AI initiatives, proactively engaging with regulatory bodies and investing in resources that align AI systems with the ethical and transparent standards stipulated by the EU AI Act.

The low frequency of articles on compliance readiness suggests that healthcare institutions may not adequately prioritize preparation for the EU AI Act. This lack of focus could result from several factors, including the complexity of regulations [4],

resource constraints [5], or lack of awareness about the Act's implications [6]. Non-compliance with the EU AI Act could lead to legal repercussions, financial penalties, and damage to institutional reputation [1]. Therefore, healthcare institutions must engage in compliance efforts proactively [5]. The formulation of AI governance policies in accordance with the EU AI Act, the performance of compliance audits to identify deficiencies, the allocation of resources for staff training on regulatory mandates and ethical AI methodologies, and the engagement with regulators, industry organizations, and other entities to exchange best practices, are all required steps in this process.

The study relies on the frequency of news articles as a proxy for institutional focus and readiness, which may only partially capture internal efforts that are publicly reported. Additionally, the data is limited to English-language sources, potentially excluding relevant articles in other European languages.

5. Conclusion

It is imperative for healthcare institutions to prioritize regulatory compliance. This approach ensures the ethical and effective implementation of AI systems, bridging the significant gap between the adoption of AI technologies in European healthcare institutions and their readiness to comply with the EU AI Act. In essence, maintaining AI in healthcare while proactively complying with the EU AI Act will not only decrease legal risks but also increase patient trust.

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