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LEGAL ANALYSIS OF ARTIFICIAL INTELLIGENCE REGULATION AS A CLINICAL DECISION SUPPORT SYSTEM IN INDONESIAN HOSPITALS: CHALLENGES, ACCOUNTABILITY, AND REGULATORY REFORM

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ABSTRACT

Background. The rapid advancement of Artificial Intelligence (AI) has transformed healthcare delivery worldwide, particularly through the development of Clinical Decision Support Systems (CDSS). AI-powered CDSS can assist healthcare professionals in diagnosis, treatment planning, risk prediction, and clinical decision-making. While these technologies offer substantial benefits in improving efficiency and accuracy, they also raise complex legal, ethical, and regulatory questions concerning accountability, patient safety, informed consent, data protection, and medical liability. This study aimed to examine the adequacy of existing Indonesian legal frameworks in regulating AI-based CDSS in hospitals and to identify regulatory gaps that may affect legal certainty and patient protection.
Research Methods. This research employs a normative juridical method. The statutory approach analyzes relevant Indonesian regulations, including: Law No. 17 of 2023 on Health, Law No. 27 of 2022 on Personal Data Protection, Law No. 11 of 2008 on Electronic Information and Transactions, Regulations concerning electronic medical records and hospital governance. The conceptual approach examines legal theories related to professional liability, product liability, patient autonomy, and algorithmic accountability. The comparative approach evaluates regulatory developments from international frameworks.
Findings. Although existing regulations concerning health services, electronic systems, personal data protection, and medical practice provide partial governance, Indonesia has not yet established a comprehensive legal framework specifically addressing AI-assisted clinical decision-making. Consequently, significant uncertainties remain regarding liability allocation, algorithmic transparency, informed consent, and institutional accountability.
Conclusion. The development of a dedicated regulatory framework for AI in healthcare that balances technological innovation with patient safety, ethical governance, and legal certainty.

Keywords: Artificial Intelligence, Clinical Decision Support System, Health Law, Medical Liability, Hospital Regulation, Indonesia.

BACKGROUND

Artificial Intelligence (AI) is increasingly transforming healthcare systems by supporting diagnostic processes, predicting clinical outcomes, assisting treatment decisions, and enhancing operational efficiency. Among the most significant applications of AI in healthcare is the Clinical Decision Support System (CDSS), a technology designed to analyze patient data and generate recommendations that assist healthcare professionals in making clinical decisions. Unlike autonomous medical systems, CDSS functions as a decision-support tool, meaning that healthcare professionals remain responsible for final clinical judgments [1].

The growing use of AI-powered CDSS reflects broader trends in digital health transformation. Hospitals worldwide are adopting AI technologies to improve diagnostic accuracy, reduce medical errors, optimize resource allocation, and support evidence-based

medicine. Recent studies indicate that AI-assisted systems can improve healthcare quality while reducing clinician workload, particularly in environments facing shortages of healthcare professionals [2]. Nevertheless, the increasing integration of AI into clinical practice raises important legal questions concerning accountability, transparency, and patient rights.

One of the most significant legal concerns involves determining responsibility when AI-generated recommendations contribute to patient harm. Traditional medical liability frameworks were developed on the assumption that clinical decisions are made exclusively by human healthcare professionals. However, when clinical judgments are influenced by complex machine-learning algorithms, the allocation of legal responsibility becomes significantly more complicated. Questions arise regarding whether liability should be borne by physicians, hospitals, software developers, or multiple parties simultaneously [3,4].

In Indonesia, digital health transformation has accelerated following healthcare modernization initiatives and the enactment of several legal instruments supporting electronic health services. The enactment of the Health Law, Personal Data Protection Law, and regulations concerning electronic medical records has created a foundation for digital healthcare governance. However, these regulations were not specifically designed to address AI-assisted clinical decision-making. Consequently, legal uncertainty persists regarding issues such as algorithmic accountability, transparency requirements, informed consent obligations, and liability for AI-related clinical errors [5,6].

Given the increasing deployment of AI technologies in healthcare, a comprehensive legal assessment is necessary to determine whether Indonesia's current regulatory framework adequately protects patients while supporting innovation. This study therefore examines the legal implications of AI-powered Clinical Decision Support Systems in Indonesian hospitals and proposes regulatory reforms necessary to ensure safe, ethical, and accountable implementation.

Existing literature has extensively examined the technical effectiveness of AI-powered CDSS and the ethical implications of AI in healthcare [2,7]. Several international studies have also explored legal liability arising from AI-assisted clinical decision-making [3,4]. However, most existing research focuses on legal frameworks in Europe, North America, or other developed jurisdictions.

Within the Indonesian context, previous studies have primarily discussed AI governance in healthcare from ethical or technological perspectives without conducting a comprehensive analysis of how existing health law, medical law, electronic system regulation, and personal data protection frameworks interact in governing AI-assisted clinical decisions [5,8]. Current scholarship lacks comprehensive legal analysis of AI-CDSS within Indonesian hospital settings, examination of legal accountability among physicians, hospitals, and AI developers, assessment of informed consent requirements for AI-assisted healthcare, evaluation of regulatory readiness for AI governance in healthcare institutions. This study aimed to examine the adequacy of existing Indonesian legal frameworks in regulating AI-based CDSS in hospitals and to identify regulatory gaps that may affect legal certainty and patient protection.

This study contributes to the literature by 1)integrating health law, digital law, and AI governance into a unified legal analysis, 2)examining AI-CDSS through the perspective of clinical accountability and patient safety, 3)evaluating regulatory gaps within Indonesia's healthcare legal framework, 4)proposing a legal governance model specifically tailored for AI-assisted clinical decision-making in hospitals.

RESEARCH METHOD

This study employs a normative juridical approach, a research method commonly used in legal scholarship to examine legal norms, principles, doctrines, and regulatory frameworks governing a particular legal issue. The normative juridical method is considered appropriate because the primary objective of this research is to analyze the adequacy of Indonesia's existing legal framework in regulating the use of Artificial Intelligence (AI) as a Clinical Decision Support System (CDSS) in hospital settings. Rather than relying on empirical observations or

quantitative measurements, this approach focuses on assessing the substance, coherence, and effectiveness of legal norms that govern the deployment of AI technologies in healthcare services.

The research primarily utilizes a statutory approach to systematically examine and interpret national laws and regulations relevant to AI-assisted healthcare services. The statutory analysis includes constitutional provisions and sector-specific legislation governing health services, medical practice, hospital administration, electronic systems, and personal data protection. The principal legal materials analyzed include Law No. 17 of 2023 concerning Health, Law No. 44 of 2009 concerning Hospitals, Law No. 29 of 2004 concerning Medical Practice, Law No. 27 of 2022 concerning Personal Data Protection, and Law No. 11 of 2008 concerning Electronic Information and Transactions, as amended by subsequent legislation. In addition, implementing regulations concerning electronic medical records, telemedicine services, and digital health transformation are also examined. Through this statutory analysis, the study evaluates whether existing regulations provide sufficient legal certainty regarding the use of AI-based Clinical Decision Support Systems, particularly in relation to patient safety, professional responsibility, informed consent, data governance, and institutional accountability.

In addition to domestic legislation, this study analyzes relevant international legal and ethical frameworks that influence the governance of AI in healthcare. Given the global nature of AI development and the absence of comprehensive national regulations specifically addressing AI-assisted clinical decision-making, international standards serve as important normative references. The study therefore reviews international instruments and guidelines, including the World Health Organization (WHO) Guidance on Ethics and Governance of Artificial Intelligence for Health, the WHO Guidance on Large Multi-Modal Models for Health, the UNESCO Recommendation on the Ethics of Artificial Intelligence, and principles developed by the Organisation for Economic Co-operation and Development (OECD) on Artificial Intelligence. These international frameworks emphasize key principles such as transparency, accountability, explainability, human oversight, fairness, non-discrimination, privacy protection, and patient autonomy. The analysis of these instruments enables the study to assess the extent to which Indonesian regulations are aligned with internationally recognized standards and best practices in AI governance.

Furthermore, the research employs a comparative legal approach to explore how other jurisdictions regulate AI-assisted clinical decision-making and allocate legal responsibility arising from the use of AI technologies in healthcare. Comparative analysis focuses on selected jurisdictions that have developed more advanced regulatory frameworks for healthcare AI, particularly the European Union, the United States, and several other countries where relevant. The study examines regulatory developments such as the European Union Artificial Intelligence Act (EU AI Act), medical device regulations applicable to AI systems, and legal approaches concerning product liability, medical malpractice, and algorithmic accountability. Comparative legal analysis also considers judicial decisions and scholarly discussions regarding liability allocation among physicians, healthcare institutions, and AI developers when adverse clinical outcomes occur. Through this comparative perspective, the research identifies regulatory best practices and lessons that may inform future legal reforms in Indonesia.

The study further incorporates a conceptual approach by examining legal doctrines and theoretical concepts relevant to AI governance in healthcare. Several legal theories are employed, including theories of professional liability, product liability, patient autonomy, informed consent, hospital liability, and good governance in healthcare. The study also draws upon concepts of algorithmic accountability, human-centered AI, and risk-based regulation to critically assess the emerging challenges posed by AI-assisted clinical decision-making. This conceptual analysis provides a broader theoretical foundation for evaluating the adequacy of existing legal frameworks and identifying normative gaps requiring regulatory intervention.

The legal materials used in this research consist of primary legal materials, including statutes, regulations, international instruments, and official policy documents, as well as secondary legal materials, such as peer-reviewed international journal articles, academic books, legal commentaries, policy reports, and publications issued by international organizations. The literature was collected through comprehensive searches of reputable academic databases,

including Scopus, PubMed, ScienceDirect, Web of Science, and Google Scholar, to ensure that the analysis reflects contemporary developments in healthcare law and AI governance.

All legal materials are analyzed qualitatively using a descriptive-analytical method. This analytical technique involves identifying relevant legal norms, interpreting their meaning and scope, examining their interrelationships, and evaluating their effectiveness in addressing legal issues arising from the use of AI as a Clinical Decision Support System in hospitals. The analysis further seeks to identify regulatory inconsistencies, legal uncertainties, and normative gaps within the existing framework. Findings are subsequently interpreted within the broader context of healthcare digitalization, patient protection, and technological innovation to formulate recommendations for future regulatory reform.

Overall, the normative juridical approach adopted in this study provides a comprehensive legal assessment of the regulatory framework governing AI-assisted clinical decision-making in Indonesian hospitals and enables a critical evaluation of whether current laws are sufficiently capable of ensuring legal certainty, protecting patient rights, promoting accountability, and supporting the responsible integration of Artificial Intelligence into healthcare services [1,3,7].

FINDINGS

The Emergence of AI-Based Clinical Decision Support Systems in Healthcare

Artificial Intelligence-based Clinical Decision Support Systems represent one of the most rapidly developing innovations in modern healthcare. These systems utilize machine learning algorithms, predictive analytics, natural language processing, and large-scale health data to generate recommendations that assist clinicians during diagnosis, treatment planning, and patient management. Unlike fully autonomous medical systems, AI-CDSS is designed to augment human judgment rather than replace it. Physicians remain responsible for evaluating AI-generated recommendations and integrating them into clinical decision-making processes [3].

The growing adoption of AI-CDSS is driven by increasing healthcare complexity and the expanding volume of clinical information that physicians must process daily. AI technologies can rapidly analyze large datasets, identify hidden patterns, and generate evidence-based recommendations that may improve diagnostic accuracy and treatment outcomes. International studies indicate that AI-assisted systems have demonstrated potential benefits in medical imaging, oncology, cardiology, intensive care medicine, and disease prediction models [2,7].

In Indonesia, AI adoption is gradually emerging in hospitals and healthcare facilities, particularly in diagnostic support, electronic health records, and nursing decision support systems. However, technological development is progressing more rapidly than legal adaptation. As a result, healthcare institutions increasingly face situations where AI tools influence clinical decisions without clear legal guidance regarding accountability, transparency, and patient protection [5].

Legal Status of AI-CDSS Under Indonesian Healthcare Law

A central legal question concerns whether AI-CDSS should be regarded merely as a medical support tool or as a participant in clinical decision-making. Existing Indonesian healthcare regulations continue to place decision-making authority and professional responsibility on healthcare professionals. Under current legal principles, physicians remain accountable for diagnoses, treatment decisions, and patient outcomes regardless of whether AI recommendations are utilized during clinical practice.

This legal position reflects the internationally recognized principle of human oversight. According to guidance issued by the World Health Organization, AI technologies in healthcare should support rather than replace healthcare professionals, and human judgment must remain central to patient care [7]. The distinction between support and substitution is particularly important because it determines how liability is allocated when adverse events occur. If AI

recommendations are considered advisory rather than determinative, physicians may remain the primary legally accountable actors [7].

However, this traditional approach becomes increasingly problematic as AI systems become more sophisticated. Advanced machine learning models often operate as "black box" systems whose internal reasoning processes are difficult for clinicians to understand fully. Consequently, healthcare professionals may rely on AI recommendations without being able to independently verify the underlying logic. This creates uncertainty regarding whether physicians should bear sole responsibility for errors generated by highly complex algorithms [1,3].

DISCUSSIONS

Legal Liability and Accountability for AI-Assisted Clinical Decisions

Legal liability represents one of the most challenging issues in AI governance. Traditional medical negligence frameworks assume that healthcare professionals directly control clinical decision-making. AI-assisted medicine introduces additional actors, including software developers, technology providers, hospitals, data managers, and system integrators. Consequently, determining responsibility for patient harm becomes substantially more complex.

Current international legal scholarship identifies three potential liability models. The first model assigns primary responsibility to physicians because they retain final decision-making authority. Under this approach, clinicians are expected to critically evaluate AI-generated recommendations before applying them to patient care. If physicians blindly follow inaccurate recommendations, liability may remain with the clinician [3,4].

The second model emphasizes product liability principles. In situations where patient harm results from algorithmic defects, programming errors, or inadequate system design, software developers and technology companies may bear legal responsibility. This approach recognizes that healthcare professionals cannot reasonably detect all technical defects within highly complex AI systems [4,9].

The third model adopts a shared liability framework involving physicians, hospitals, and developers. This model is increasingly viewed as the most realistic because AI-assisted clinical decisions result from interactions among multiple actors. Hospitals determine procurement decisions, developers design algorithms, and clinicians apply recommendations within patient care contexts. Therefore, legal accountability may need to be distributed according to each actor's contribution to the harmful outcome [1,3].

In Indonesia, however, no specific legal provisions currently define liability allocation for AI-assisted medical decisions. This regulatory gap creates uncertainty for healthcare professionals, hospitals, and patients seeking legal remedies following adverse events.

Informed Consent, Data Protection, and Patient Rights

The use of AI-CDSS also raises significant concerns regarding patient autonomy and informed consent. Traditionally, informed consent requires physicians to explain the nature of medical interventions, potential risks, expected benefits, and available alternatives. When AI systems contribute to clinical decision-making, additional information may be necessary to ensure that patients understand the role of technology in their care.

Patients may reasonably expect disclosure regarding whether AI systems are involved in diagnosis, treatment planning, or risk assessment. Such disclosure promotes transparency and respects patient autonomy. Furthermore, explainability becomes increasingly important because patients may wish to understand how recommendations affecting their healthcare were generated [7,10].

Data protection constitutes another critical issue. AI systems require large volumes of health information to function effectively. The collection, processing, storage, and sharing of patient data th erefore raise significant privacy concerns. Indonesia's Personal Data Protection Law provides an important legal foundation for safeguarding sensitive health information.

Nevertheless, AI applications create additional challenges related to secondary data use, algorithm training, cross-border data transfers, and cybersecurity vulnerabilities [5,7].

Hospitals implementing AI-CDSS must therefore establish robust governance mechanisms that ensure compliance with privacy obligations while maintaining public trust. Failure to protect patient data may result not only in regulatory sanctions but also in reputational damage and diminished confidence in digital health innovations.

Regulatory Reform and Future Governance of AI-CDSS in Indonesia

The findings indicate that Indonesia currently regulates healthcare services, electronic systems, personal data protection, and medical practice through separate legal frameworks. While these regulations provide partial governance, they do not adequately address the unique characteristics of AI-assisted clinical decision-making.

Future regulatory reform should focus on establishing a dedicated legal framework for healthcare AI. Such regulation should clearly define AI-CDSS, establish standards for clinical validation, require algorithmic transparency, determine liability allocation mechanisms, and mandate ongoing post-market monitoring of AI systems. International experience suggests that effective AI governance requires balancing innovation with patient safety and accountability [7,10].

Additionally, hospitals should be required to establish AI governance committees responsible for risk assessment, ethical review, and oversight of AI implementation. Regulatory authorities should also develop certification procedures ensuring that AI systems meet safety, effectiveness, and fairness standards before deployment in clinical settings. Ultimately, the goal of regulation should not be to restrict technological innovation but to create legal certainty that promotes responsible adoption. A comprehensive governance framework can enhance patient trust, support healthcare professionals, and encourage sustainable innovation in Indonesia's healthcare system.

This study has several limitations that should be acknowledged when interpreting its findings. First, this research adopts a normative juridical approach, which primarily focuses on the analysis of legal norms, statutory regulations, legal doctrines, and international regulatory frameworks. Consequently, the study does not empirically examine the actual implementation of Artificial Intelligence (AI)-based Clinical Decision Support Systems (CDSS) in Indonesian hospitals. The findings therefore reflect a legal and doctrinal assessment rather than real-world experiences, operational outcomes, or institutional practices associated with AI utilization in healthcare settings.

Second, the study relies predominantly on secondary legal materials**,** including legislation, policy documents, international guidelines, academic literature, and legal commentaries. Although these sources provide a comprehensive understanding of the existing regulatory framework, they may not fully capture the practical challenges encountered by healthcare professionals, hospital administrators, AI developers, patients, and policymakers during the implementation of AI-assisted clinical decision-making systems. The absence of primary data collected through interviews, surveys, or stakeholder consultations may limit the study's ability to reflect diverse perspectives regarding legal accountability and regulatory needs.

Third, the regulatory landscape governing AI in healthcare is evolving rapidly at both national and international levels. Indonesia has not yet enacted specific legislation dedicated exclusively to AI governance in healthcare, while international standards and regulatory approaches continue to develop. Consequently, some of the legal issues identified in this study may change as new regulations, guidelines, or judicial interpretations emerge. The findings should therefore be interpreted within the context of a dynamic and continuously evolving technological and legal environment.

Fourth, although this study incorporates a comparative legal approach, the comparative analysis is limited to selected international frameworks and jurisdictions. Differences in healthcare systems, legal traditions, technological infrastructure, institutional capacity, and socio-cultural contexts may affect the applicability of foreign regulatory models to Indonesia.

Therefore, caution should be exercised when generalizing international best practices or directly transplanting regulatory approaches from other countries into the Indonesian healthcare system.

Fifth, this research primarily examines AI-based CDSS from a legal and regulatory perspective and does not comprehensively address the technical performance of AI systems, including algorithmic accuracy, clinical effectiveness, interoperability, cybersecurity resilience, or software validation processes. These technical dimensions are essential for assessing patient safety and the overall effectiveness of AI-assisted healthcare but fall beyond the scope of this legal analysis.

Sixth, the study does not specifically investigate the perceptions, readiness, and acceptance of AI technologies among healthcare professionals and patients. Factors such as digital literacy, trust in AI systems, professional attitudes, and organizational readiness may significantly influence the successful adoption of AI-assisted clinical decision-making in hospitals. The absence of these behavioral and institutional dimensions may limit the comprehensiveness of the analysis.

Finally, this study does not empirically evaluate potential disputes, malpractice claims, or judicial decisions involving AI-assisted medical practices, largely because such cases remain limited in Indonesia. As AI technologies become more widely integrated into healthcare services, future legal disputes may provide important jurisprudential guidance regarding liability allocation and accountability mechanisms.

Despite these limitations, this study offers an important contribution to the emerging scholarship on AI governance in healthcare by providing a comprehensive legal assessment of Indonesia's existing regulatory framework and identifying key normative gaps requiring future regulatory reform. Future studies are encouraged to adopt empirical, interdisciplinary, and mixed-methods approaches involving healthcare practitioners, patients, policymakers, and technology developers to generate a more holistic understanding of the legal, ethical, technical, and institutional implications of AI implementation in Indonesian hospitals.

CONCLUSION

Artificial Intelligence-powered Clinical Decision Support Systems have significant potential to improve healthcare quality, efficiency, and clinical outcomes in Indonesian hospitals. However, their increasing integration into healthcare delivery raises complex legal challenges concerning accountability, liability, informed consent, transparency, and data protection. Existing Indonesian legal frameworks provide only partial regulation and do not specifically address AI-assisted clinical decision-making.

This study concludes that Indonesia requires a dedicated legal framework governing AI-CDSS to ensure patient safety, legal certainty, and ethical implementation. Such regulation should clarify liability allocation among physicians, hospitals, and developers; establish transparency requirements; strengthen informed consent mechanisms; and ensure compliance with personal data protection standards. By developing comprehensive AI governance, Indonesia can support technological innovation while safeguarding patient rights and public trust.

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