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Research on Global Health Governance and AI

LIABILITY FRAMEWORKS FOR ARTIFICIAL INTELLIGENCE IN HEALTHCARE: A COMPARATIVE ANALYSIS OF VIETNAM AND INTERNATIONAL STANDARDS

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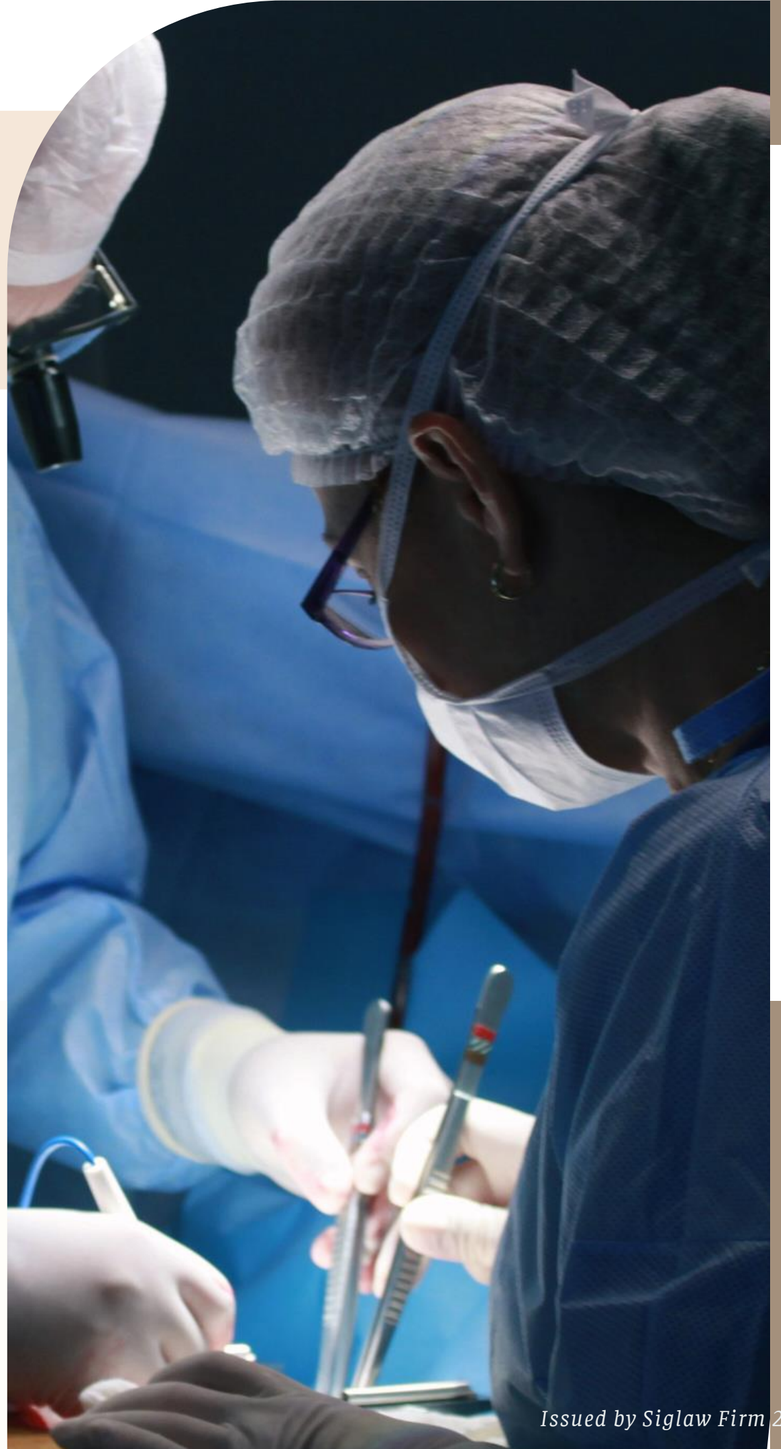

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TABLE OF CONTENTS

1. INTRODUCTION

THE POTENTIAL APPLICATIONS OF AI IN HEALTHCARE

- AI is revolutionizing medicine, not just as a support tool but as an integral part of modern healthcare systems.
- AI facilitates personalized healthcare, predicts disease risks, optimizes medical resources, and enhances treatment effectiveness.
- Key examples:
  - IBM Watson: Analyzes complex medical data, supports doctors in making personalized treatment decisions, and is applied in oncology, pharmaceuticals, and clinical research.
  - Google DeepMind: Develops medical image processing algorithms for early detection of eye diseases and cancer, and is used in genetic research.
- Other AI technologies: Deep learning, reinforcement learning, big data processing, and diverse applications in various medical fields.

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LEGAL CHALLENGES OF AI IN HEALTHCARE

- “Black box” AI: Complex deep learning models and neural networks, making it difficult to explain decision-making processes, hindering error tracing and ensuring transparency.
- Ambiguity of liability: Blurred lines between product liability (manufacturers) and medical malpractice (healthcare facilities, medical personnel), creating difficulties when AI causes errors.
- Fragmented legal framework: International standards are emerging, with varying AI regulations across countries and regions, requiring a multidimensional approach.
- Impact of opacity on patient autonomy.

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AI APPLICATIONS IN HEALTHCARE AND LEGAL GAPS IN VIETNAM

- Vietnam: AI applications in major hospitals (Vinmec, Hospital 108) for diagnostic imaging and other fields.
- Legal gap: Lack of specific regulations on AI in healthcare, making it difficult to define liability.
- Need for a flexible legal framework, clear liability delineation, and reference to international experience (FDA, EU AI Act).
- Detailed analysis of AI projects at Vinmec and Hospital 108, including technologies used and achieved results.
- Discussion of the potential and challenges of implementing AI in the Vietnamese healthcare system.
- Analysis of current laws and decrees related to healthcare, technology, and personal data protection.

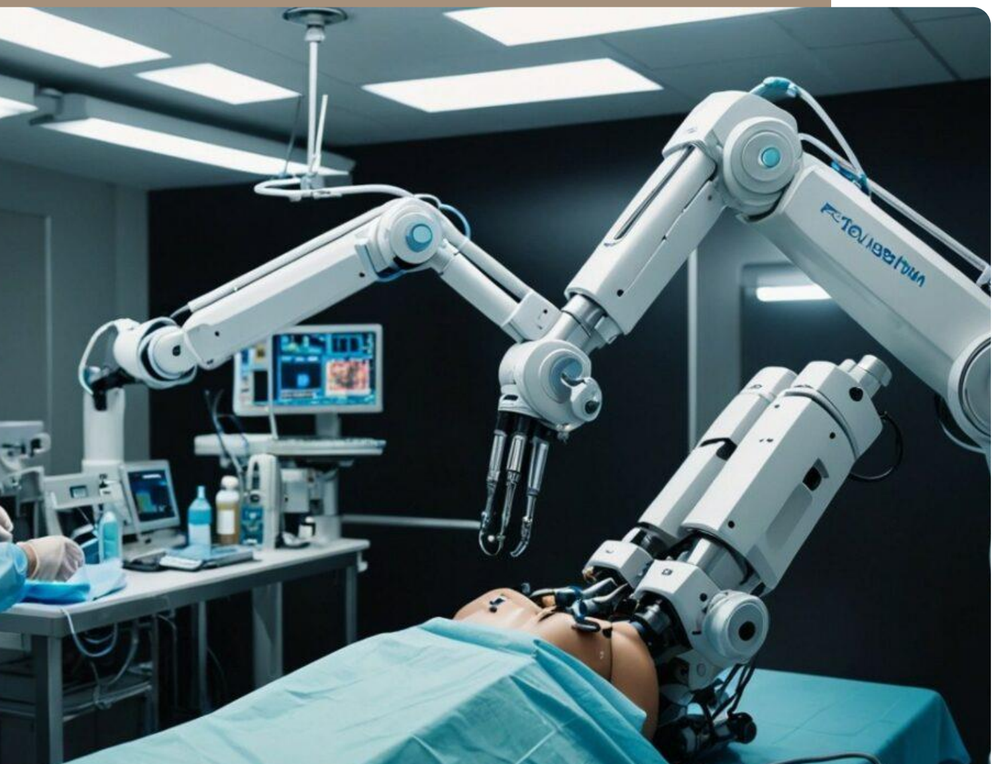
- Shortcomings and contradictions in current regulations when applied to the AI context.
- The draft personal data protection law and its impact on the use of AI in healthcare.
- This gap requires a flexible liability-sharing mechanism between AI developers and healthcare facilities using AI in patient treatment.
- This model should be based on the principle of fairness and shared responsibility, where stakeholders are held accountable according to their respective roles. Vietnam can draw on AI legislation from other countries, such as the US FDA and the EU AI Act, to develop an approach tailored to its specific context.
- This research examines international AI standards, providing recommendations for Vietnam to address AI liability in healthcare, ensuring patient rights and promoting safe AI applications.

REQUIREMENTS FOR A CLEAR AND FLEXIBLE LEGAL FRAMEWORK

- AI's self-learning capabilities render current regulations obsolete, necessitating a flexible update mechanism.

- The rapid development of AI poses legal and ethical challenges, requiring appropriate regulations.

2. Product liability VS Medical malpractice: INTERNATIONAL PERSPECTIVE



2.1. PRODUCT LIABILITY

- Medical AI: Products with legal liability, similar to medical devices and pharmaceuticals.
- Analysis of complex scenarios when AI makes incorrect decisions, causing patient harm.
- Discussion of different legal liability models and the need for a multidimensional approach.
- Overview of international AI standardization efforts, including initiatives by WHO, OECD, and ISO.
- Analysis of differences between AI regulations across countries and regions.

2. Product liability VS Medical malpractice:

INTERNATIONAL PERSPECTIVE

2.1. PRODUCT LIABILITY

- **USA approach:**
  - FDA: Classifies AI as Software as a Medical Device (SaMD) with high risk, requiring compliance with strict approval processes (PMA, 510(k)).
  - Legal risks: Design flaws (biased algorithms, biased training data), inadequate risk warnings.
  - Analysis of SaMD approval processes, including PMA and 510(k).
  - Discussion of potential legal risks and how manufacturers can mitigate them.

2. Product liability VS Medical malpractice:

INTERNATIONAL PERSPECTIVE

2.1. PRODUCT LIABILITY

- **EU approach:**
  - EU AI Act: Strict regulations for high-risk medical AI, requiring transparency, human oversight, and risk management.
  - Product Liability Directive: Developers are liable if AI causes harm.
  - Draft AI Liability Directive strengthens consumer rights.
  - High-risk AI regulations, including requirements for conformity assessment, risk management, and human oversight.
  - EU AI Act's impact on AI developers and healthcare facilities.
  - The need for technical standards and quality control procedures.

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2.2. MEDICAL MALPRACTICE

- Healthcare facilities and medical personnel are liable if they fail to comply with standards of care when using AI.

USA approach

- Liability under state tort law, complex when determining liability when using AI.
- Liability models in each region.
- Differences and similarities between approaches.

UK approach

- "Bolam test": Assesses whether a doctor's actions align with professional standards, becoming complex when AI is involved in the care process.
- The changing role of doctors in the AI era.

EU approach

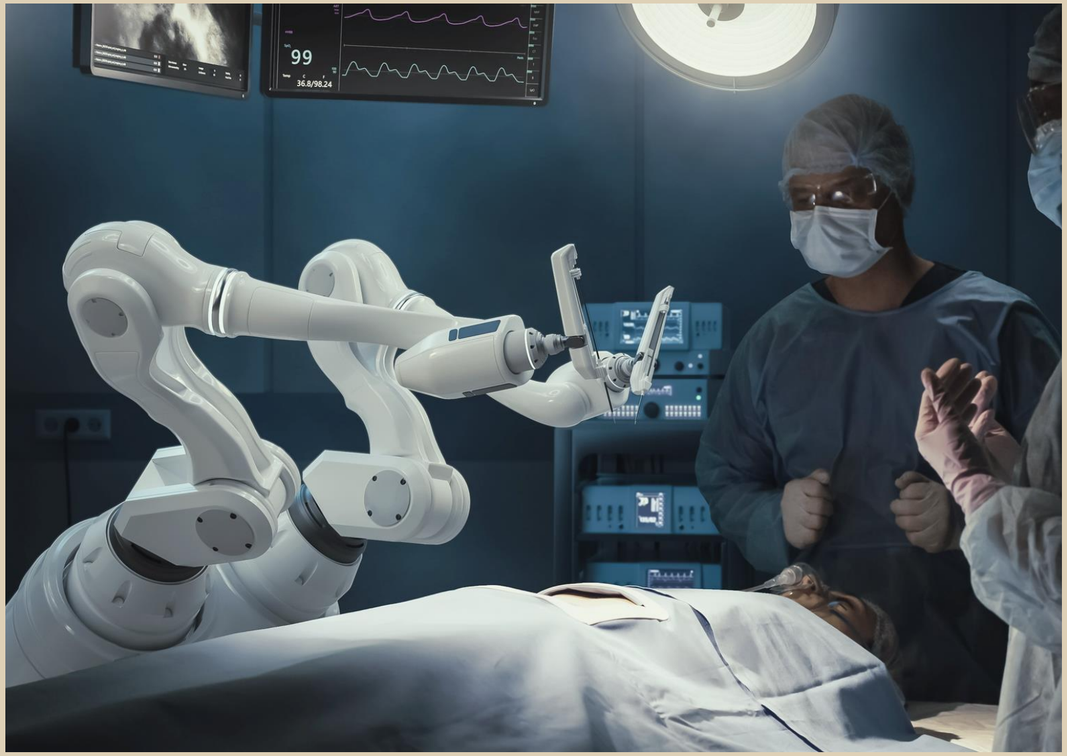
- EU AI Act: Regulates the liability of doctors, medical personnel, and healthcare facilities, requiring AI training, conformity assessment, oversight, and human intervention rights.
- Issues related to AI training for medical personnel, AI oversight, and doctor decisions.

2.3. LIABILITY CHALLENGES IN AI-BASED HEALTHCARE

- Challenges: “Black box” nature, continuous learning, biased data, defining “standards of care”, patient privacy, and data protection.
- Issues related to design flaws, biased training data, and risk warnings.
- Discussion of the need for technical standards and quality control procedures.
- Case studies:
    - IBM Watson for Oncology: Errors in cancer treatment, raising complex legal issues of liability.
    - Google DeepMind: Violations of patient data privacy, raising issues of personal information protection. Laws and regulations regarding personal data protection, such as GDPR and HIPAA, the necessity of data security measures and patient data control.

3. Product liability VS Medical malpractice:

VIETNAM'S PERSPECTIVE



Legal gaps in medical AI in Vietnam, requiring regulations tailored to the actual situation.

3.1. PRODUCT LIABILITY

- Legal basis: Decree 98/2021/ND-CP (AI as "medical software"), Civil Code, Law on Protection of Consumer Rights, Law on Product and Goods Quality.
- Challenges: Lack of specific regulations on medical AI, leading to difficulties in determining liability when AI causes errors.
- Exemption of liability: Clause 1, Article 35 of the 2023 Law on Protection of Consumer Rights and Point d, Clause 1, Article 62 of the 2007 Law on Product Quality allow for exemption of liability if product defects are undetectable by global scientific and technological standards, creating difficulties when applying AI.
- Liability delineation: Need to clearly define the liability of AI developers, healthcare facilities, medical personnel, and other stakeholders.
- Need for specific regulations on AI in healthcare.

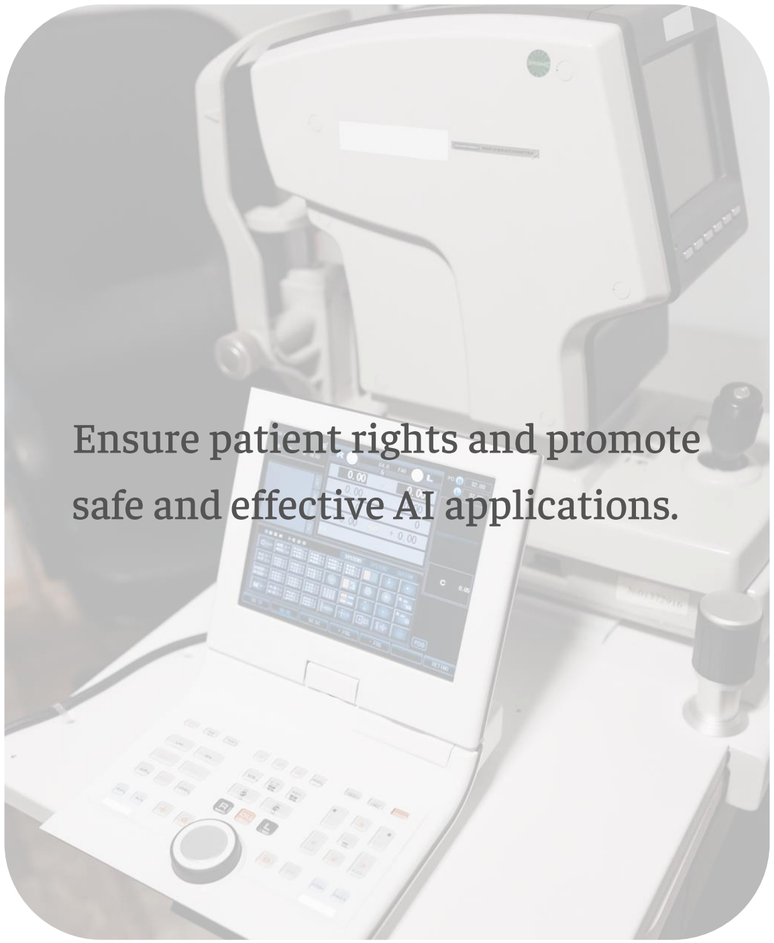
3.1. PRODUCT LIABILITY

- The 2023 Law on Medical Examination and Treatment and the 2015 Civil Code regulate the liability of healthcare facilities and medical personnel.
- Challenges:
  - “Unintended risks” vs. “professional errors” when using AI: Difficult to distinguish when AI makes decisions beyond the control of medical personnel.
  - Lack of AI training for medical personnel: Hinders AI monitoring and effectiveness evaluation.
- The necessity of regulations on AI training for medical personnel and AI oversight.

4. CONCLUSION AND RECOMMENDATIONS

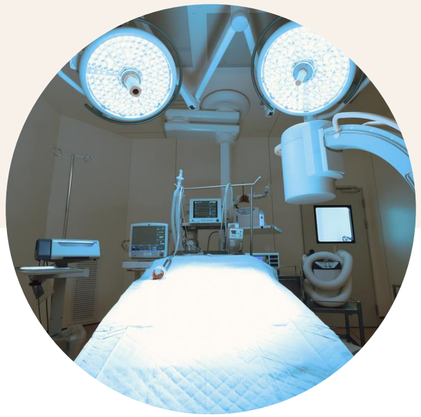
Need to develop a flexible legal framework with clear liability division among AI developers, healthcare facilities, medical personnel, and other stakeholders.

Refer to international experience (FDA, EU AI Act) to develop a framework suitable for Vietnam's specific context.



Ensure patient rights and promote safe and effective AI applications.

Propose principles and standards for an AI legal framework in healthcare in Vietnam.



Discuss the need for stakeholder participation, including AI developers, healthcare facilities, medical personnel, and patients.

Propose models and best practices from different countries and regions.

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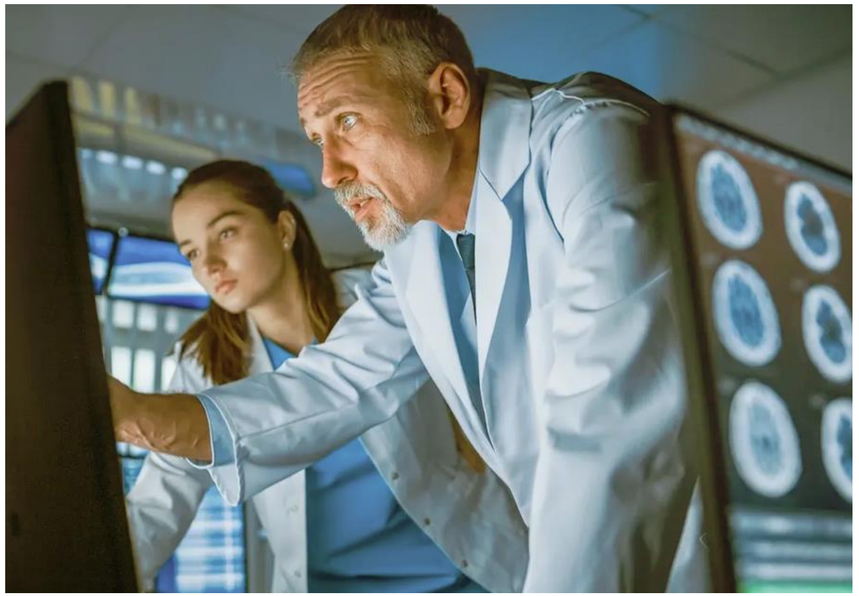
Emphasize the need for transparency, accountability, and human oversight.



Discuss the role of education and training in promoting safe and effective AI applications.

THANK YOU FOR LISTENING!

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