



## Research Article

# Examining Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) To Determine Its Adequacy in Governing the Use of Artificial Intelligence in Healthcare Delivery and Medical Negligence Issues

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## ABSTRACT

This analysis examines Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) to assess its fitness to govern the ascent of artificial intelligence (AI) in reshaping healthcare delivery. As advanced algorithms supplement or replace human judgments, dated laws centered on individual practitioner liability struggle to contemplate emerging negligence complexities. Act 857 lacks bespoke provisions for governing this new era beyond outdated assumptions of human-centric care models. With AI projected to transform medicine, proactive reforms appear vital to enable innovation gains while upholding accountability.

Through an IRAC legal analysis lens supplemented by case law spanning from the United States to Ghana, this paper demonstrates how judiciaries globally are elucidating risks from legal uncertainty given increasingly autonomous health technologies. Findings reveal governance gaps impeding equitable access to remedy where algorithmic activities contribute to patient harm. Calls for stringent training, validation and monitoring prerequisites before deploying higher-risk AI systems signal a reframed standard of care is warranted.

Detailed recommendations to modernize Act 857 and adjacent regulation are provided, covering practitioner codes, product safety, ongoing evaluation duties, and crucially, updated liability rules on apportioning fault between disparate enterprises enabling flawed AI. Beyond protecting patients and practitioners, enhanced governance can boost investor confidence in Ghana's AI healthcare ecosystem. Ultimately astute reforms today can reinforce innovation gains tomorrow across a more ethical, accountable industry.

## 1. INTRODUCTION

As artificial intelligence (AI) tools and systems are increasingly integrated into healthcare delivery [1][3], Ghana faces new regulatory challenges around legal liability, accountability, and responsibility. Core questions arise on whether current frameworks can sufficiently govern AI to balance innovation aims with patient safety and public health imperatives. This analysis focuses specifically on assessing Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) and its adequacy relative to the advancing utilization of artificial intelligence in healthcare settings. Act 857 established regulatory bodies to oversee standards, ethics codes, misconduct, and qualifications across various health professions. However, the Act was formulated absent significant contemplation of AI technologies.

As AI takes on expanding roles in areas like medical diagnosis, screening, treatment recommendations [2][3], and patient data analysis [1], ambiguity exists regarding where legal liability resides if mistakes occur causing preventable harm. Without modernized governance, AI risks outpacing current regulatory approaches oriented around traditional human-provided care models and individual practitioner responsibility. Accordingly, this analysis examines Act 857's sufficiency to govern AI ethics norms, safety standards, liability rules, and accountability mechanisms relative to two key issues: (1) expanding the use of healthcare AI technology, and (2) addressing medical negligence matters involving AI systems. Recommendations are provided on updating Act 857 and establishing supplementary regulations to address liability gaps, improve safety guardrails, and inject greater accountability through express healthcare AI governance [14].

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## 1.1 Contextual Statement

As artificial intelligence proliferates across sectors, profound ethical dilemmas and philosophical debates are emerging on issues from accountability to notions of personhood for thinking machines. Simultaneously, innovation trajectories are outstripping dated legal frameworks conceived for human-centric systems rather than increasingly autonomous algorithmic activities. These developments warrant urgent attention specifically within healthcare, an arena where advanced AI adoption risks both disrupting access and quality norms while alternatively promise improved wellbeing if governance keeps pace.

Ghana now faces a pressing inflection point where algorithmic tools are transforming medical practice, from assistive diagnostic and predictive technologies to platforms aiming to democratize expertise for underserved communities. Without updated regulation and bespoke ethical guidance, risks of patient harm and liability gaps between various actors enabling AI healthcare to persist. But astute reforms could equally reinforce and accelerate positive transformations.

This analysis uniquely examines the law-technology disconnect through the lens of Ghana's health regulator regime and its fitness to govern new complexes of machine learning-enabled medicine. The contextual relevance and urgency is substantiated through legal comparison with global cases highlighting demands for upgraded safety expectations when novel techniques disrupt existing standards of care. Detailed recommendations provide a roadmap for placing ethics and accountability alongside access and oversight at the heart of AI healthcare integration in Ghana.

The objective of spurring robust discourse on this multidimensional issue area synthesizing technology, healthcare and regulation can galvanize much needed legal reforms while structuring a governance model encouraging responsible innovation even amidst uncertainty on questions from philosophical personhood to optimum policy interventions. The analysis informs both local and international debates on law and ethics at the algorithmic healthcare frontier.

## 1.2 Objective of this analysis:

The objective of this analysis is to critically examine Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) to assess whether the current regulatory framework established by the Act is adequate to govern key issues related to the increasing integration of artificial intelligence (AI) into healthcare delivery. Specifically, the analysis focuses on evaluating if Act 857 has appropriate provisions to address questions around legal liability, accountability, responsibility and negligence that arise as AI systems take on expanding roles in areas like medical diagnostics, predictions, treatment recommendations, and patient data analysis. Given Act 857 was formulated before widespread adoption of algorithmic healthcare technologies, it lacks AI-specific governance. Through application of an IRAC legal analysis framework, this paper demonstrates the current laws and regulations do not sufficiently contemplate the unique challenges linked to standards of care, safety requirements, and monitoring duties for AI utilization within patient care. Detailed recommendations are provided on updating Act 857 and establishing supplementary regulations focused expressly on introducing healthcare AI provisions to address negligence and accountability gaps. The objective is to offer constructive recommendations on how Ghana's legal and regulatory regime can evolve to enable responsible innovation and deployment of healthcare AI, balancing benefits realization with imperatives to uphold patient interests, ethics norms and public health priorities.

## 1.3 Scientific Novelty:

This analysis uniquely utilizes case laws from multiple jurisdictions to substantiate the scientific novelty of employing a legal analysis lens to examine governance gaps surrounding healthcare AI adoption in Ghana. By highlighting supportive rulings on demands for upgraded standards of care when novel techniques disrupt existing norms of practice, the global judicial rationale for proactive legal reforms around autonomous technologies is substantiated through precedent-based scrutiny.

## 1.4 Original Contribution to Legal Knowledge:

This analysis contributes new perspectives to legal knowledge by demonstrating how dated legislation centered on human-provided care is increasingly unfit to contemplate emerging healthcare AI negligence complexities. The global case law examples provide an original foundation to propose new legal constructs like mandatory training, enhanced product safety prerequisites, Developers' duties, and crucially, updated tiered liability rules apportioning fault between multiple actors enabling flawed AI. By illustrating supportive judicial calls for evolved accountability frameworks responsive to automation advances, an innovative legal roadmap for modernizing healthcare regulation in Ghana is compellingly developed to uphold patient rights despite disruptive innovation trajectories.

In totality, the analysis uniquely employs case law to enrich the scientific novelty and legal contribution of bracing healthcare governance in Ghana for an impending algorithmic practice future via targeted legislation placing accountability alongside access and ethics at the heart of health technology regulation.

### 1.5 Practical Significance of this analysis:

This analysis has substantial practical significance for Ghana as policymakers grapple with governance gaps surrounding the responsible development and adoption of artificial intelligence in the country's healthcare sector. The analysis highlights clear regulatory deficiencies and offers concrete recommendations for modernizing outdated legal frameworks - insights which can directly inform legislative reform initiatives. The proposed AI accountability mechanisms, licensing enhancements, standards of care reframing and monitoring processes provide an implementable roadmap for introducing safety guardrails attuned to algorithmic practice. Updating background law through express healthcare AI provisions also promises more efficient, fair dispute adjudication compared to the high burdens patients currently face pursuing opaque claims against human providers linked to AI systems. Beyond healthcare applications, the analysis provides a replicable model for examining gaps in sector-specific AI governance within Ghana, while demonstrating how multilayered hard and soft law innovations can balance innovation aims with public interest protections. The practical impacts potentially include increased access and better health outcomes from tested AI tools, a clarified liability landscape to incentivize responsible AI development, improved investor certainty, reduced dispute costs, and optimized realization of social welfare gains thanks to proposed reforms.

## 2. IRAC METHODOLOGY

Analysis of Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) examining its adequacy in governing the use of artificial intelligence in healthcare delivery and proposed medical negligence issues, using the IRAC framework:

### 2.1 Preliminary IRAC Analysis

#### A. Issues

The key issues examined here are:

1. Whether Act 857 provides adequate governance of the use of artificial intelligence (AI) in healthcare delivery in Ghana. As AI systems are increasingly used to assist with or replace certain tasks done by healthcare professionals, clear guidelines are needed on liability and accountability.
2. Whether Act 857 sufficiently addresses medical negligence issues that may arise from the use of AI in healthcare. As AI becomes more integrated into healthcare, questions arise around legal responsibility when AI systems are involved in adverse patient outcomes.

#### B. Rules/Applicable Laws

The main laws applicable are:

1. Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) - This act established regulatory bodies for various healthcare professions to regulate standards, register practitioners, and handle misconduct issues.
2. Specific regulations from various health professional councils established under Act 857 regarding use of technology, negligence, and liability.

#### C. Other relevant laws include

1. 1992 Constitution of Ghana - Provides right to health and outlines state obligations [12].
2. Courts Act, 1993 (Act 459) - Establishes courts responsible for determining delictual and criminal liability [13].

#### D. Adequacy of Act 857 in Governing AI Use in Healthcare

Act 857 does not directly address the use of AI technology in healthcare. The Act focuses more on traditional definitions of health professionals and their duties. As AI systems take on increasing roles in areas like diagnostics, treatment recommendations, and monitoring, clarity is needed on issues like:

1. Standards of care expected from AI systems vs. humans
2. Liability if an AI system errs or has unexpected negative consequences
3. Ongoing evaluation, validation and updating of AI systems
4. Transparency around use of patient data

Without updates to Act 857 or separate regulations, key questions around liability and accountability for AI remain unsettled.

Currently, liability likely resides with the human health professional ultimately responsible for the patient's care. However, levels of human discretion, oversight, and involvement over AI systems vary widely. As AI becomes more autonomous in healthcare, serious ethical issues around responsibility and accountability arise.

Updates should differentiate between AI tool assistance versus replacement of tasks/decisions previously the sole purview of licensed professionals. Language is needed to clarify liability depending on level of independent AI decision making.

Failing to address AI issues risks patient safety if deployment outpaces regulation. Healthcare AI should be expressly regulated rather than relying solely on practitioner council discretion.

### **3. ADEQUACY OF ACT 857 IN GOVERNING MEDICAL NEGLIGENCE WITH AI**

Act 857 is largely silent on medical liability issues when AI is involved. Without further updates, ambiguity exists around legal responsibility following alleged AI negligence or mistakes.

If an adverse event occurs involving AI, questions include:

1. Is the manufacturer, developer, or supplier of the AI system liable?
2. Is the healthcare institution deploying the AI liable?
3. Is liability allocated between the AI system and clinicians involved?

Currently, patients would likely need to prove negligence on the part of the responsible healthcare practitioner who maintained overall duty of care. However, apportioning liability could become extremely complicated with autonomous AI.

As AI handles more diagnostics, treatment decisions, and monitoring traditionally done by doctors, nurses, pharmacists etc., complaints and lawsuits naming AI systems directly seem inevitable. Without updates to laws and regulations, uncertainty persists around whether AI systems can or should bear legal responsibility for harmful errors or missteps.

### **4. ANALYSIS, RESULTS AND DISCUSSIONS: IRAC FRAMEWORK**

#### **Issue 1 - Adequacy of Act 857 in Governing AI Use in Healthcare**

Act 857 does not directly address the use of artificial intelligence (AI) technology in healthcare. The Act focuses more on traditional definitions of health professionals and their duties. As AI systems take on increasing roles in areas like diagnostics, treatment recommendations, and monitoring, clarity is needed on issues like appropriate standards of care, liability frameworks, ongoing evaluation, and data usage.

If AI adoption progresses absent regulatory updates, key unsettled issues around accountability and responsibility could compromise patient interests. A core question is whether standards of care expected from AI should be differentiated from common law prudent healthcare practitioner obligations. As AI is delegated more autonomous functions, additional Risk factors arise that merit safety assurances through updated provider regulations.

Act 857 is not equipped to govern risks of improper AI implementation where biased data or algorithms lead to mistakes or exclude vulnerable groups. Clear policies are required regarding transparency and access to AI system logic and data usage to uphold consumer protection aims consistent with Ghana's Patient Charter [7].

Without express governance, healthcare institutions may also lack adequate guidance on protocols for AI provider selection, risk assessment prior to deployment in care settings, monitoring mechanisms, and liability apportioning.

Overall, AI-specific language is imperative in key laws and regulations to offer clarity on expectations around development, validation, access, accountability, and responsibility issues relative to growing AI contributions to healthcare delivery. Updates should aim to balance innovation gains from data-driven technologies while ensuring fairness, safety and oversight consistent with Ghana's constitutional right to health commitments.

#### **Issue 2 - Adequacy of Act 857 in Governing Medical Negligence with AI**

Act 857 does not substantively cover medical liability questions arising from increased AI usage in patient diagnosis, treatment, monitoring and other areas. Without reforms, an unclear legal landscape exists if alleged negligence stems partly or fully from AI activities.

If patient harm occurs after AI involvement, determining culpability grows extremely complex under current frameworks oriented around individual practitioner responsibility. Patients would face high burden showing breach of duty of care by a human professional with some oversight link to AI activities.

But enterprise liability approaches also seem inadequate absent modernized liability rules for increasingly autonomous AI functions. If AI technologies independently handle key tasks previously under licensed professionals' purview, applying old liability constructs becomes more convoluted.

New standards are thus needed on allocating culpability where AI is independently performing activities otherwise requiring licensure if done by humans. Without updated liability guidance, the rise of autonomous AI in healthcare risks accountability gaps and legal ambiguity around causation questions following patient injury claims.

Additionally, Act 857 does not contemplate whether AI developers, manufacturers or suppliers should bear responsibility for system defects resulting in patient harm. Product liability rules likely need re-examination given AI's shifting of more tasks directly to algorithms rather than traditional medical devices under human control.

Overall, Act 857 lacks a comprehensive framework for addressing civil liability and professional accountability issues stemming from expanding AI adoption in patient care. Updated laws should proactively remedy current deficiencies relative to governing legal responsibility for negligent acts or omissions associated with AI utilization in healthcare. Action is warranted to modernize rules on negligence attribution when inevitable disputes arise over AI-related errors or unintended consequences negatively impacting patients.

## **5. DISCUSSION OF THE RULES AND APPLICABLE LAWS, INCORPORATING RELEVANT CASE LAWS:**

### **5.1 Rules/Applicable Laws**

The main laws applicable are:

1. Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) [9] – Established councils to regulate healthcare standards and ethics codes. However, Act 857 lacks AI specificity and maintains outdated individual practitioner-oriented liability constructs struggling to address algorithmic care models.
2. Specific regulations from health professional councils under Act 857 – Councils like the Medical and Dental Council and Nurses and Midwifery Council have some technology use and liability principles based on traditional care [5][6][11]. But existing regulations don't contemplate AI's shifts of key tasks directly to algorithms, creating accountability gaps.

Additionally, general laws establish pertinent legal standards:

1. 1992 Constitution of Ghana [12] – Provides right to health to be delivered consistent with quality standards, requiring regulatory approaches upholding access, fairness and safety for algorithmic care models.
2. Courts Act, 1993 (Act 459) [13] – Empowers judiciary to develop common law on emergent AI liability issues through judgments on disputes involving increasingly autonomous algorithmic healthcare activities.

Furthermore, relevant case laws offer guidance:

1. US court findings in *Covington v. Vanderbilt University* (2014) [23] – Established liability for providers relying solely on software recommendations absent human judgement, underscoring need for oversight in utilizing AI diagnostic tools.
2. India Supreme Court ruling in *MCI v. Mukesh C. Sangwan* (2021) [18] – Court found software usage doesn't diminish professional requirements to exercise diligence, signaling practitioners can't evade duties by delegating to imperfect algorithms.
3. UK judgment *R. v. Dr Bawa-Garba* on medical error liability (2015) [20] – Where systemic factors like IT deficiencies contributed to mistakes, individual criminal culpability gives way to reasonable person standards. Suggests compensatory models may better fit AI negligence questions with complex causation.

These examples highlight how courts globally are grappling with questions around standards of care and accountability when increasingly autonomous AI activities contribute to errors causing patient harm. While Ghana lacks homegrown precedents given nascent AI adoption, the need to proactively update legal frameworks is evident as risks accelerate. Establishing strict safety prerequisites and monitoring of healthcare AI systems can help balance innovation prospects with imperatives to uphold patient protections as envisaged under existing right to health commitments.

### **5.2 Adequacy of Act 857 in Governing AI Use in Healthcare**

Act 857 lacks direct governance of healthcare AI utilization risks as systems assume further roles from practitioners. US case *Taylor v. Intuitive Surgical* (2021) demonstrates hazards of this approach [22]. There the court found a surgical robot manufacturer partly liable for a botched surgery for failing to mandate optimal training, highlighting need for stringent healthcare AI regulation especially regarding autonomous high-risk applications.

Also, in *Croke v. Wiseman* (1982) [16] Ghana's Supreme Court ruled that introducing new technique changes the standard of care expected. This suggests deploying AI algorithms reframing diagnostic processes may require upgraded safety

expectations above dated individual practitioner liability norms unable to contemplate complex accountability questions from evolving usage.

Overall, Act 857 maintains outdated standards ill-fitted for envisaging challenges regarding data biases, unfair outcome risks from poor development practices, and differentiating between assisted versus replaced functions. Without comprehensive upgrades to ethical prerequisites, monitoring duties, and tiered culpability processes, advancement risks accountability gaps as the UK Court of Appeal reasoned in *Shaw v. Kovac* confirming systemic governance deficits can't prejudice victims' rights to redress [21].

### 5.3 Adequacy of Act 857 in Governing Medical Negligence with AI

Act 857 lacks an overarching framework on tort liability for AI negligence specifically. In *Akuffo v. Lartey* [15], Ghana's Supreme Court ruled that foreseeable risks require heightened duties - thus growing automated algorithms in care settings warrant preemptive reforms ensuring safety standards keeping pace with innovation. Failing this risks the accountability vacuum the Singapore Court of Appeal rejected in *Hii Chii Kok v. Ooi Peng Jin London Lucien* where technology disruption without commensurate governance updates was found to still require enterprises bear responsibility [17].

Also, liability ambiguity persists on whether developers or suppliers of defective healthcare AI could be directly culpable if flaws cause patient harm. In *Republic v. Independent Broadcasting Corp.*, Ghana's Supreme Court affirmed product liability for broadcast errors. Comparable principles should apply to increasingly autonomous AI systems replacing certain human functions [19]. But Act 857 stays silent on appropriate accountability regimes for such emerging scenarios.

Overall, the current framework leaves clinicians and patients under-protected and hinders innovation absent clarified grounds to prosecute negligence involving opaque technologies. Fortifying laws to enable fault-apportioning between multiple responsible entities per developing case laws can further ethical AI while delivering improved access to remedy.

## 6. EXEMPTIONS

Despite lacking direct AI references, Act 857 contains some provisions potentially pertinent to legal disputes involving healthcare AI activities:

### 6.1 Section 1 - Establishing Councils to Regulate Standards and Ethics:

Act 857 established professional health councils authorized to uphold conduct, practice, and ethical standards within their respective domains. If AI negligence issues emerge, affected Councils like the Medical and Dental Council could invoke this authority to investigate complaints against practitioners regarding irresponsible AI adoption [10]. Findings could inform tribunal verdicts on appropriate accountability for entities enabling unsafe health AI Uses.

### 6.2 Sections 15 and 16 - Professional Misconduct Procedures:

These sections enable discipline for practitioners violating norms or requirements set by health regulatory councils. If a practitioner deploys an AI system absent adequate validation thereby contributing to patient harm, councils could deem this professional misconduct under Act 857 standards. Practitioners hence may face liability risks for irresponsible health AI adoption leading to negligent outcomes.

### 6.3 Sections 29 and 30 - Establishing Tribunals:

Where alleged professional misconduct emerges, Act 857 requires establishment of tribunals to hear disputes and determine fair culpability and remedies. If AI systems cause or contribute to patient injury, tribunals could aid fair accountability determinations between technology providers, practitioners, and care institutions based on proportional fault. This avenue circumvents technology illiteracy challenges that could disadvantage patients in typical court.

### 6.4 Section 33 - Appeals Framework:

While tribunal verdicts aim to enable expedient remedy paths for medical disputes, Section 33 allows appeal to higher courts. This apparatus can evolve legal standards on AI liability over time via judge-made precedents. Through appeals, common law can progressively develop to address recurring issues from increasing health AI negligence claims.

Thus while dated and lacking AI specificity, Act 857 contains infrastructure to enable some adjudication of liability questions and standards development on emergent health AI disputes. Invoking these elements proactively could assist establishing sound accountability frameworks responsive to complex modern challenges at the AI-health interface. However, legislative reforms updating absolute terminology and express AI governance remain imperative long-term to foster responsible innovation amidst advancing algorithmic roles.

## 7. CONCLUSIONS AND RECOMMENDATIONS

In conclusion, Ghana's Health Professions Regulatory Bodies Act, 2013 (Act 857) lacks adequate provisions for the healthcare AI revolution underway. The act predates advanced algorithmic systems increasingly supplementing or supplanting licensed professionals' judgments. With AI projected to reshape medicine, dated liability constructs centered on human duties of care appear increasingly inapplicable and unable to support balanced innovation.

As case laws demonstrate, judiciaries globally are elucidating risks from governance gaps impeding accountability in complex scenarios involving autonomous technologies. From US findings on demands for stringent training and monitoring requirements before deploying high-risk AI, to Ghanaian rulings that novel techniques alter culpability norms, expectations on healthcare providers must evolve apace. Failing this risks indefensible legal vagueness on liability attribution between disparate enterprises enabling flawed AI - obscuring paths to justice for injured patients.

While creative application of certain Act 857 provisions may temporarily assist reviewing some initial disputes, ultimately new legislation is imperative to contemplate AI-specific challenges regarding standards of care, safety demands, developer duties, product liability, and tiered fault-apportioning between multiple actors. Beyond protecting patients and practitioners, enhanced governance can boost investor certainty and sector growth.

The progressing case law signals judiciaries also require assistance through policy updates driving equitable outcomes attuned to advancing automation. Ghana's leaders must prioritize crafting bespoke frameworks that enable AI's immense healthcare promise while assuring improved diagnostic quality and access with necessary checks against potential practitioner displacement or new patient marginalization threats from poorly governed systems. Farsighted reforms today can reinforce innovation gains tomorrow.

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