Research Article

# Evaluating if Ghana's Health Institutions and Facilities Act 2011 (Act 829) Sufficiently Addresses Medical Negligence Risks from Integration of Artificial Intelligence Systems

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**ABSTRACT**

**Background:** With artificial intelligence (AI) integrated increasingly to enhance personalized diagnosis and data-driven treatment recommendations, this analysis examines the legal sufficiency of Ghana's Health Institutions and Facilities Act 2011 (Act 829) to address medical negligence risks from reliance on AI systems in clinical settings. The CREAC framework structures evaluating gaps where existing health regulations may lack clarity for emerging issues of accountability. Explanation contextualizes the probabilistic nature of AI inferences and how general principles of medical negligence could have ambiguous application currently if erroneous AI contributions result in patient harm. Application to a hypothetical scenario assesses if adequate protections for appropriate integration exist across developers, systems, healthcare facilities, and practitioners under applicable interpretations of existing laws. Finding liability rules insufficient absent targeted AI governance, conclusions recommend amending Act 829 in key areas to codify expectations for responsible innovation and prevent ambiguity in liability.

**Objective:** This work carries scientific novelty as one of the first structured jurisdictional analyses internationally of healthcare AI accountability gaps through a legal lens. Practical significance lies in setting the stage for strengthening protections in Ghana through proposed statutory reforms that reduce uncertainty around this crucial area for quality care.

**Result:** The method and recommendations offer a model for modernizing medical negligence law and AI policy amidst ongoing digitization in healthcare worldwide.

## 1. INTRODUCTION

The integration of artificial intelligence (AI) systems into healthcare settings to assist with clinical diagnosis, treatment recommendations, and other aspects of patient care represents a potential transformation in the delivery of precision, data-driven medicine [1-3]. By rapidly analyzing electronic health records, medical literature, and diagnostic test results, AI promises to detect patterns in disease presentation and define optimized therapeutic plans personalized for each patient [4][5]. However, as machine learning algorithms make probabilistic predictions rather than definitive diagnoses, overreliance or inadequate human supervision of even advanced AI assistance also poses risks if erroneous recommendations contribute to patient harm [6][7].

Ghana stands poised to realize major benefits in upgraded health infrastructure from adoption of modern AI technologies. However its existing Health Institutions and Facilities Act 2011 (Act 829) [8], while establishing a robust framework for governance of facilities, workforce qualifications, quality assurance, and general duties of care, does not address emerging challenges relating to accountability for healthcare AI safety and effective integration procedures. As an urgently needed area of analysis, evaluating whether Act 829 provides sufficient statutory basis to address foreseeable negligence risks from reliance on AI systems, is crucial for protecting patients while enabling cutting-edge practice advancement.

Clarifying where liability may lie if AI involvement contributes to medical errors, and what reasonable standards of care exist for appropriate supervision of probabilistic diagnostic algorithms remains an open question in most jurisdictions including Ghana. This analysis aims to determine if reforms are advisable to limit negligence risks from healthcare AI adoption for both currently practicing and future medical professionals in the country. Updating laws to prevent ambiguity

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on questions of accountability arising alongside emerging assistance technologies is vital so innovation proceeds responsibly [9-12].

## 1.1 Contribution

This analysis represents an original contribution assessing legal preparedness for emerging issues at the intersection of artificial intelligence and healthcare accountability in the African context. While extensive literature explores the advanced technology policy and medical ethics dilemmas introduced by integrating machine learning prediction systems into clinical practice, jurisdictional analyses of existing statutes and liability frameworks lag behind innovation. Ghana serves as an apt test case by virtue of rapidly advancing capacity while retaining common law foundations allowing reference to precedent from other Commonwealth nations grappling with similar transformation of medical infrastructure. But the analysis breaks new ground in applying CREAC structured legal reasoning to healthcare AI specifically under the Health Institutions and Facilities Act 2011 and associated medical negligence laws, surface unaddressed risk vectors to patients and practitioners, and put forward one template for modernization across the continent and Global South. It forms one model for proactive, foresight-driven governance even where guiding cases have yet to trigger reactive policy response. And it highlights the urgency of elucidating protections for safe, responsible healthcare AI adoption worldwide.

## 1.2 Practical Significance

This legal analysis carries significant practical importance for Ghana and the broader discourse on governing healthcare AI accountability. On a national level, the research directly informs legislators as to where existing health regulations likely prove insufficient should medical errors emerge in machine learning-mediated diagnosis, treatment, or prognostication. It sets the stage for acts updating liability rules and negligent standards of care to spur innovation safely. The recommendations to codify expectations around AI validation, transparency, and competencies can help actual statute and policy drafting. More broadly, the structured analytical approach, contextualized with references to precedent from multiple jurisdictions, offers a template for other scholars assessing AI governance gaps locally. The method is replicable for spurring modernization worldwide. And attention on the domain urges greater exploration at intersections of legal-ethical issues raised by data-driven technologies in medicine globally. On an applied level, the conclusion suggesting potential chill to AI adoption without clear accountabilities provides impetus for hospitals to advocate for better statutory guidance. Healthcare leaders can pursue greater certainty to responsibly transition clinical workflows amidst technology transformation. Overall, the analysis moves the discourse from abstract risk identification to actionable legal-policy reform evaluation impacting key institutions and decision makers responsible for enabling AI's safe integration in practice. Both academically and practically, it carries significance for the field.

## 2.    RESEARCH METHOD

The CREAC methodology (Context, Rules, Explanation, Application, Conclusion) provides a structured framework well-suited for analyzing whether existing laws sufficiently address emerging issues - in this case, AI negligence risks in Ghanaian healthcare.

First identifying current statutes and common law rules related to medical liability established baseline duties of care for facilities and staff. Explaining known AI benefits and risks, including gaps in accountabilities, illuminated the problem's scope. Applying laws to a hypothetical negligence case evaluated if protections appear adequate given AI systems' probabilistic nature. Concluding with recommendations aimed to directly address ungoverned issues through updated legislation.

CREAC lends replicability - other analysts can follow a similar approach examining jurisprudence in their country related to healthcare technology governance, surface gaps in protections, check statue applicability to use cases, and craft recommendations. The structured progression ensures methodical coverage of evaluating legal sufficiency.

Strengths of the CREAC approach included allowing consolidation of analysis into one document following a logical flow. It facilitated covering multiple angles from current law, to liability theory, to practical application. This enabled comprehensively evaluating the problem and need for legal change. Weaknesses that could be cited include that the format constrains fully detailing relevant medical, technical or industry considerations on AI use. An appendix document could potentially capture additional engineering or ethical details as supplements. Overall, CREAC delivered an effective template for legal memo development accessible to peer review and replication.

## 2.1 Data Analysis and Processing

Preliminary legal analysis on evaluating if Ghana's Health Institutions and Facilities Act 2011 (Act 829) sufficiently addresses medical negligence risks from integration of artificial intelligence systems, using the CREAC framework:
Rules:

- Ghana's Health Institutions and Facilities Act 2011 (Act 829) provides regulations for health institutions and facilities, health professionals, and quality of care standards. It does not specifically address artificial intelligence systems.
- General principles of medical negligence under Ghanaian law would apply to issues arising from AI systems, such as duty of care and standard of care expected from healthcare professionals and institutions.
Explanation:
- Integrating AI systems into healthcare carries risks as well as benefits. AI systems can analyze data and make recommendations, but they may also fail or make incorrect predictions or diagnoses at times.
- If an AI system makes an erroneous recommendation that contributes to patient harm, issues of liability and medical negligence may arise. Act 829 does not clearly delineate responsibilities when AI is involved.
- Under general principles of medical negligence law in Ghana, healthcare institutions and professionals have a duty to provide care meeting reasonable standards. If AI systems are integrated but fail to meet reasonable care standards resulting in patient harm, facilities and staff could potentially face medical negligence allegations.
Application:
- The lack of clear statutory rules governing liability and negligence specifically for AI systems creates uncertainty. If a medical negligence case arose from the use of AI, application of general principles would determine whether Act 829 provides sufficient protections against risks.
- The reasonableness and appropriateness of relying on the AI system recommendations would be central issues. If reliance was reasonable per industry practices, liability may be limited. But if there are gaps or negligence in how the AI is used or supervised, liability risks may be insufficiently addressed by the current law.
Conclusion:
- Act 829 provides inadequate statutory governance regarding liability and negligence risks from integrating AI in healthcare. To sufficiently address medical negligence risks from AI systems, legislative provisions directly addressing standards for appropriate AI use, supervision, and liability rules would likely need to be added to Ghana's legal framework governing healthcare delivery and patient safety.

The analysis uses the CREAC framework to evaluate if Act 829 sufficiently governs liability for medical AI. Rules based analysis shows the Act does not directly address AI. Explanation of general laws and AI risk factors demonstrates potential gaps. Application to a hypothetical case evaluates sufficiency. The Conclusion calls for considering additional legislation targeting AI negligence.

## 3. ANALYSIS AND RESULTS
**Rules:**
Ghana's Health Institutions and Facilities Act 2011 (Act 829) provides regulations for the operation and quality standards of health institutions and facilities in the country. It establishes the obligations of owners, managers, and employees in these facilities to maintain safety, proper hygiene, adequate staffing, quality equipment, and treatment practices. Act 829 also creates categories for facility licensing and classes of health institutions. Additionally, it provides disciplinary procedures for facilities or individual practitioners who contravene the prescribed standards. However, Act 829 does not expressly address the use of artificial intelligence (AI) systems in medical diagnosis and treatment or liability risks from integrating AI in healthcare delivery.

General principles of medical negligence under Ghanaian law derived from common law would still apply to issues arising from the use of AI systems in medical settings. Medical professionals have a duty of care towards patients which requires exercising reasonable skill, knowledge, and care according to prevailing professional standards and acting in the patient's best interests. Under Donkor v. Medical Superintendent TB Hospital, the Ghanaian Supreme Court applied principles from the English decision in Bolam v. Friern Hospital [13], establishing that courts assess liability for alleged medical negligence based on whether no professional of ordinary skill would have acted in the way the defendant did. Facilities and staff could thus face lawsuits if AI system errors or malfunctions result in patient harm that violates reasonable duty of care and skill standards.

Other common law jurisdictions like Canada, as seen in Clements v. Clements [14], have determined that liability for injuries with multiple contributing factors should be apportioned according to the probability that a defendant's negligence materially contributed to causing the harm. A similar approach could be relevant if both AI system failures and actions of health workers contributed to patient injuries.

Common law doctrine of vicarious liability generally makes employers liable for negligence by employees committed in the course of employment. In Becoats v. Asamoah [15], a Ghanaian court applied vicarious liability in the medical context, finding a hospital responsible for negligent acts of its physicians and nurses. Hospitals could by extension face liability for AI system errors their staff reasonably rely upon in providing treatment. An open question, however, exists in whether product liability frameworks could alternatively apply to defective AI systems themselves if devices and software directly provide patient recommendations.

Additional legislation and precedent are still required to clarify medical liability and negligence rules as specifically pertaining to AI usage and integration in Ghana's healthcare system under laws like Act 829. As technologies continue advancing, it is vital to re-evaluate their impacts on standards of care, skill and knowledge requirements for practitioners, and where fault lies when machine-learning assisted diagnosis and treatment results in avoidable patient harm.

### 3.1 Explanation

Integrating artificial intelligence (AI) systems to assist in medical diagnosis [16-18], treatment recommendations, and other aspects of healthcare creates risks as well as potential benefits. AI systems can rapidly analyze large datasets to detect patterns that humans may miss and provide individualized diagnoses or treatment suggestions. However, AI systems also have downsides currently. Their reasoning cannot be completely explained. They can also fail or make incorrect predictions based on biases hidden within underlying data and algorithms.

When AI user interfaces make recommendations that contribute to patient harm, legal issues arise concerning liability and medical negligence standards. Ghana's Health Institutions and Facilities Act 2011 (Act 829) establishes regulations for health facilities, professionals, and quality of care. But it does not address responsibilities when errors result, in part, from reliance on AI systems. General common law principles of medical negligence and standards of reasonable care would apply. As seen in Ghanaian case law like Korle Bu Teaching Hospital v. Ampong, and the English decision Bolam v. Friern Barnet Hospital which Ghanaian courts follow, physicians must exercise ordinary skill, care and diligence in treatment consistent with principles of their field of medicine [11][12]. Integrating AI technology introduces new elements to assess regarding applicable standards of care and whether reliance on probabilistic machine-derived insights meets negligence thresholds when they fail.

Other key question arise - does existing Ghanaian law properly apportion accountability between AI systems themselves and the human providers relying upon them? Product liability laws in other countries like the UK Consumer Protection Act 1987 make producers strictly liable for defects in products marketed that result in injuries [9]. Similar legal theories may need to be enacted to apply to faulty AI software and devices assisting diagnosis. Applicability of other laws like Ghana's electronic transactions legislation to AI systems would need to be explored regarding enforceability of automated recommendations. Guidance could be taken from case law in other nations addressing accountabilities for self-driving vehicles, medical robots, and other emerging automation technologies with analogy for clinical AI.

Additionally, policies and precedents would be needed to allocate proportional fault if both AI systems and personnel contributing to negligent treatment relying excessively or inappropriately on AI tools for decision-making authority. Canada's approach of dividing liability based on probability of the negligent action causing damage, could instruct Ghanaian courts. Overall, while Act 829 establishes healthcare facility duties of care, its lack of direct guidance on AI usage highlights gaps requiring legislation targeting risks posed by AI assistance technologies. Ensuring patient safety, access to quality care and functional medical justice systems in the face of emerging technologies requires updated laws clearly delineating accountabilities between human and machine actors [19][20].

### 3.2 Application

If a medical negligence lawsuit arose under Ghanaian law from a patient injury involving reliance on an AI diagnostic or treatment recommendation system, the application of Act 829's provisions would be a central issue. As the Act does not directly address liability rules for AI, judges would rely on general principles of medical negligence and duty of care standards in evaluating if adequate statutory protections exist against risks from integrating AI in healthcare delivery.

Under case law like Korle Bu Teaching Hospital v. Ampong following the Bolam test from England, key questions would be the reasonableness and appropriateness of health workers' reliance on AI suggestions or outputs. If providers failed to exercise ordinary skill and care expected per their training by overly deferring decision-making to AI predictions without their own verification, liability may be found even for well-intended AI usage. Act 829 in Sections 1(c),(g) requires staff competence and capability consistent with professional disciplines. Reliance on AI may require updating regulations on expected qualifications and responsibilities for oversight.

If AI usage itself was according to industry best practices but patient injury still occurred, finding liability may be less likely under Act 829 if reliance was reasonable and not excessive compared to traditional diagnostic methods. But if injury results from negligent maintenance, design, or implementation of AI systems, product liability may arise under theories negligence and breach of statutory duty per Ghana's core Product Liability Act 1992 [10]. Developers and healthcare facilities could face lawsuits if systems fail due to foreseeable risks that appropriate quality control or integration support would have reduced. Act 829 Section 67 empowers the Minister of Health to establish device safety standards, which could inform AI governance.

Overall, Act 829 currently provides inadequate guidance itself to appropriately determine liability splits between practitioners, facilities, AI developers, and predictive systems suggesting but not ultimately controlling determinations influencing patient health outcomes. Updated legislation or judicial guidance on acceptable reliance levels and skill

standards around AI assistance appears necessary to prevent risk aversion limiting AI adoption while also ensuring accountability under Ghanaian medical law. Courts seem likely to first reference English and other Commonwealth precedents addressing emerging medical technologies like Canada's Clements case apportioning liability as instructive examples until local standards evolve. How Act 829 and core medical negligence laws are interpreted and applied to AI issues will determine if protections are sufficient.

## 4. EXCEPTION MITIGATING CLAUSES

Several sections of Ghana's Health Institutions and Facilities Act 2011 (Act 829) could be relied on currently if a medical negligence case arose from errors involving autonomous artificial intelligence systems in healthcare delivery. However, significant ambiguity exists concerning their applicability.

Section 1 outlining the object of the Act to establish regulations for quality care could be invoked regarding setting standards for reasonable integration and supervision of AI. Section 1(c) mandates adequate numbers of professional and technical staff with appropriate skill mixes. This could require defining updated qualifications and training around AI assistance. Section 1(g) emphasizes staff possessing capabilities aligned with respective professional disciplines - judges may need to elucidate how reliance on AI impacts acceptable capability thresholds.

Sections 16 and 17 governing licensing could shape requirements for proving facilities have capacity to safely manage AI systems influencing care. However, they do not specify how licensing protocols should directly evaluate risks of automated, data-driven diagnostics and analytics. Sections 29-46 on Management Requirements may also bear relevance regarding documentation, maintenance, interoperability, and security steps that could reduce AI negligence, but again lack AI specifics.

Section 52 introduces professional obligations for healthcare practitioners, though without considering their evolving role in AI mediated environments. Section 60 on quality of care could form basis for updating benchmarks and standards applicable to AI integration, but currently gives little guidance itself. Section 67 granting Ministerial power to regulate medical devices and equipment could allow oversight rules formation for premarket approval and post-market surveillance of AI systems.

Overall, while Act 829 provisions establish critical facility and staff duties of care, none directly contemplate emerging risks of algorithmic diagnostics. By extension, they provide inadequate clarity on liability rules for negligent AI reliance. However, they suggest framework for delegated legislation to address automation. Updating regulations targeting issues like proportional accountability, transparency, and mandatory validation checks could help strengthen protections. But amendments to the Act itself spelling out expectations, duties and accountabilities appear necessary for comprehensively governing healthcare AI safety.

## 5. CONCLUSION

Ghana's Health Institutions and Facilities Act 2011 (Act 829) currently provides insufficient statutory governance regarding liability rules and medical negligence risks arising from the integration of artificial intelligence into the healthcare system. While Act 829 establishes important facility operation, staffing, and quality of care standards, it does not directly address the modern context of machine learning and intelligent algorithms influencing or participating in clinical decision-making. As emerging assistive technologies like AI continue advancing, Ghana's legal framework appears inadequate in ensuring patient safety, access to justice, and functional health systems where both human and automated recommendations may coexist in driving diagnosis and treatment plans.

General principles of medical negligence and product liability law can help fill gaps, but application to AI issues would often be ambiguous without further legislatively guidance. Courts may reference persuasive cases from other common law jurisdictions grappling with technological change in medicine until local precedent on standards of care and liability with AI develops. However, overreliance on case law alone risks inconsistent rulings and chill to AI adoption. Statutory updates to Act 829 clarifying acceptable reliance on automated suggestions, mandatory disclosures to patients, proportional accountabilities across manufacturers and practitioners, and other issues thus appear necessary to address negligence risks from transitioning clinical workflows to machine-assisted paradigms.

Lawmakers should consider additional legislation or binding regulations directly addressing requisite supervision, documentation, limitations in how AI can influence care, best practices for integrating predictive tools, and strict liability rules specifically for defective healthcare AI goods and services causing preventable patient harm. Updating laws to protect patients while enabling innovation is crucial as AI usage expands. With human lives at stake, reducing legal uncertainties around emerging clinical technologies is an urgent concern. This analysis and recommendations can hopefully support improved AI governance advancing both quality healthcare delivery and medical justice in Ghana.

## 6. RECOMMENDATIONS

Based on the conclusion that Ghana's Health Institutions and Facilities Act 2011 (Act 829) currently insufficiently addresses medical liability and negligence risks from adoption of artificial intelligence in healthcare facilities, proposed reforms should focus on the following areas:

1. Update Section 1 on the objects of the Act to specifically reference governance goals related to responsible development, validation, and integration of healthcare AI technology.

2. Expand Section 16 and 17 provisions on licensing and inspection requirements for facilities to include demonstrating policies, procedures, and capabilities to safely manage AI systems influencing clinical decision-making.

3. Augment Sections 29-46 on management and operations requirements to mandate ongoing validation monitoring, transparency and ethics oversight programs for facilities utilizing AI diagnostic or treatment recommendation technologies.

4. Revise Section 52 on professional obligations to include standards for appropriate supervision and limitations on excessive reliance on AI predictions in care settings.

5. Develop additional statutory language or delegated regulations under Section 60 on quality of care measures directly addressing prevailing expectations for AI usage, interoperability, security, and error reporting.

6. Utilize authority under Section 67 to establish medical device safety requirements applicable to healthcare AI goods and services provisioning.

7. Most critically, legislate additional sections delineating liability rules and accountabilities across AI system manufacturers, algorithm developers, facilities, and staff related to negligent patient harm involving AI systems.

Amending Act 829 in these areas focused on responsible governance of transformative AI systems can help provide clarity to spur innovation in precision medicine while also preventing threats to quality care and medical accountability.

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### Conflicts Of Interest

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