Babylonian Journal of Artificial Intelligence
Vol. 2024 , **pp**. 14–19
DOI: https://doi.org/10.58496/BJAI/2024/003 ISSN: 3006-5437
https://mesopotamian.press/journals/index.php/BJAI

Research Article

Analyzing Ghana's Pharmacy Act, 1994 (Act 489) Regarding Quality Control and Negligence Liability Measures for Artificial Intelligence Pharmacy Systems

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Article info

Article History

Received 23 Nov 2023
Revised 18 Dec 2023
Accepted 10 Jan 2024
Published 15 Feb 2024

Keywords

Artificial Intelligence
Pharmacy Automation
Healthcare Law
Liability Gaps
Algorithm Oversight

Abstract

The objective of this systematic review was to assess the adequacy of current medication management in Ghana considering the risks posed by increased artificial intelligence (AI) automation in pharmacies worldwide A qualitative comparative approach was used despite reviewed the Ghana 1994 Pharmacy Act against recognition of AI challenges and international governance guidelines . The results revealed flaws in terms of quality prerequisites, transparency checklists and liability mechanisms developed for AI systems compared to existing regulations of the manual process. Outdated approaches to patient care that fail to ensure patient safety or address threats to the accuracy of recommendations from data collection biases and technical errors. Proposed changes include a requirement for usability testing before approving AI pharmacy deployments and the creation of a review board to review post-implementation systems for validity. Updating regulations to deal with modern equipment puts innovation and responsible regulation in the fast-paced healthcare industry. This study contributes significantly to preliminary research on AI policy readiness in the Ghanaian legal context, and suggests a feasible methodology for exploring qualitative differences for use in companies and countries competing for technology a disturbing, increasingly beyond the date code. Early government reform helps keep pace with the realities of adoption.

1. INTRODUCTION

The Ghana Pharmaceuticals Act 1994 (Act 489) established the Pharmacy Commission to regulate and license pharmacies and professional pharmacies in Ghana but the current law does not address the emerging issues of automation and artificial intelligence (AI) technology While AI pharmaceuticals systems are becoming increasingly global, the distinction between quality control and liability differentiation is clearly evident in Ghanaian law [1-3]. In recent years, AI tools for healthcare have grown rapidly. AI pharmacy systems can automate medication dispensing, inventory management, and medication recommendations [4][5]. Research projects a 31% annual growth rate in the global AI healthcare market through 2028 [6]. However, Ghanaian law preceded this technology. The Pharmaceutical Act 1994 emphasizes physical facilities, professional certification, and routine pharmacy practices but lacks provisions for the adoption of AI systems or auditing systems As the use of AI pharmacy systems increases [7] . The current Ghanaian regulatory framework does not adequately address Further research is needed to ensure patient safety and accountability for the possibilities of automation [8-10]. The changes should mandate validation of systems and continued audit of algorithmic recommendations prior to implementation. Liability laws are not defined in relation to errors or issues arising from AI systems.

1.1 Practical Significance

This analysis will highlight gaps in current law regarding emerging technologies in pharmacy practice. Recommendations could inform development of supplementary protocols and guidelines by Pharmacy Council to safeguard quality and account for AI-related risks. Other health oversight bodies may extrapolate suggestions for nationwide AI health standards.

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1.2 Scientific Novelty

There is little scholarship examining AI regulation, especially in developing country contexts. This study takes an initial step analyzing pharmacy laws versus AI utilization in Ghana specifically. Findings may prompt further investigation into balancing innovation policy with appropriate governance mechanisms for healthcare AI locally and beyond.

1.3 Objectives

1. Analyze deficiencies in quality control and liability provisions of Pharmacy Act 1994 concerning AI systems
2. Highlight patient safety and accountability risks associated with AI pharmacy automation
3. Propose regulatory and policy interventions Ghana's Pharmacy Council could implement to better oversee AI utilization.

Other researchers exhibit parallel approaches when evaluating policies in comparison to technological development processes. Vasquez-Brust et al. [11], used a comparative gap search to focus on the implementation of regulations in several Latin American countries regarding emerging data governance requirements. Otto examined the relevance of Indonesian laws in the context of the growing digital finance industry, citing outdated consumer protection laws [12] . Kumar is the name. Also looked at Indian regulatory preparedness for healthcare AI adoption models, comparable to the niche of this study [13] . As innovation spreads across countries and economies, early policy assessments of the adequacy of regulations and enforcement agencies against observable implementation enable governance reform evidence-based for contemporary issues rather than relying on past issues. It can match patterns responsibly.

2. METHODOLOGY

This systematic study used a qualitative approach to examine the gaps in the Ghana Drugs Act 1994 regulations against the emerging issues of artificial intelligence (AI) automation in the pharmacy This includes a comparative review of international AI governance principles and existing laws against known risks consistent with reported challenges and recommendations to the contexts of the stable sector , flaws or deficiencies in national legislation against practice standards and liability determinations results issue. The methodology focused on inductive coding of potential legal gaps from the collected literature and deductively verifying the relevance of the identified issues to the Ghanaian system based on a close reading of the law. Evaluating the appropriateness of state regulations for changes in technology use is replicable for dynamic systems beyond health and given a literature review where appropriate for specific risks. In particular, research that measures business AI adoption trends and existing regulatory accounting mechanisms can provide governance visibility globally in areas such as financial development or communications facing modernization.

3. RESULTS AND DISCUSSIONS

Current Quality Control Provisions in Ghana's Pharmacy Act 1994

Ghana's Pharmacy Act 1994 established protocols for drug preparation and dispensation to protect public health. The law regulates registration, standards, inspections and discipline. However, the acceleration of automation and artificial intelligence (AI) utilization in pharmacy globally has outpaced Ghanaian oversight mechanisms for emerging technologies.

1. Registration Requirements

The Pharmacy Act contains the prerequisites for pharmacists to operate or operate a pharmacy [14], which are listed in Part II. According to section 8, owners must obtain appropriate licenses and the premises must meet specified physical conditions before the Pharmaceutical Council will issue a license to operate (1). While there are simplifying standards, there are no prerequisites for specifically addressing the use of automation or AI systems as part of their registration process. International organizations advise pre-adoption health technology assessments to demonstrate the efficacy of AI and to validate data management techniques [20]. Ghanaian legislation preceded the recent guidelines, lacking mandatory review of AI tools as a pre-registration requirement for pharmacies. Evaluation systems will help monitor algorithmic recommendations to patients.

2. Practice Standards

This ordinance defines the rules for pharmacies and the use of medicines. Supervision requirements for students or recent graduates are strengthened per section 15 (1). Standards govern the storage, labelling, storage and inclusion of those described in Paragraphs 16 to 21. For example, each product supplied must include instructions and precautions for use in

Sec 18 (1,3) include or pharmacies face disciplinary action, up to a minimum fine of ¢500,000 [~$ 75 USD] per offense (2). While these rules encourage accountability in manual processes, AI systems pose risks when it comes to data manipulation or technical errors. International organizations have endorsed principles for transparent AI design, accountability and human monitoring in the context of health care (OECD 2019). Ghanaian legislation precedes AI-specific guidance on the safeguards or reasonable care expected for automated delivery technologies. This ordinance defines the rules for pharmacies and the use of medicines. Supervision requirements for students or recent graduates are strengthened per section 15 (1). Standards govern the storage, labelling, storage and inclusion of those described in Paragraphs 16 to 21. For example, each product supplied must include instructions and precautions for use in Sec 18 (1,3) include or pharmacies face disciplinary action, up to a minimum fine of ¢500,000 [~$ 75 USD] per offense (2). While these rules encourage accountability in manual processes, AI systems pose risks when it comes to data manipulation or technical errors. International organizations have endorsed principles for transparent AI design, accountability and human monitoring in the context of health care (OECD 2019). Ghanaian legislation precedes AI-specific guidance on the safeguards or reasonable care expected for automated delivery technologies.

3. Inspections

Section VIII empowers the appointees of the medical board to inspect pharmacies as well as practices and certificates of doctors. Section 37 allows incidental inspections while Section 35 requires annual renewal of permits, facilitating regular monitoring of working conditions (1,2). Investigators may collect samples or documents and violators will be disciplined by a fine of up to ¢2 million [~$300 USD] or suspension pursuant to counter-section 36 (1, 3, 4) (3). Although the Council has the right to inspect, the legislation does not expressly include an inspection of operating systems or equipment. As machines enhance physician support, new AI-compliant surveillance techniques can enhance medication management. Early policy adoption and periodic algorithmic audits through enhanced monitoring systems will support active governance.

4. Enforcement

The Commission may impose penalties for violations under Part VII including declaration of offenses in accordance with section 28 (1, 3) and fines or suspension of licenses in accordance with sections 29 and 30 (4).) indicates the. Repeated or serious violations may give rise to a criminal charge under section 31(1). While these features encourage compliance, they focus more on human responsibility than AI systems. It is clear that violations of behavioral standards due to algorithmic problems are not subject to existing disciplinary procedures that place liability on specific employees. A new protocol could clarify the extent of regulation applied to AI systems by focusing on developers in addition to operators.

5. Emerging Issues

In summary, the Ghana Pharmaceuticals Act of 1994 left predictable provisions for automation [21] . The regulations focus on registrants' physical and craft policies. The use of AI poses additional risks in terms of data privacy, system security, and accuracy of recommendations. Without adequate quality control or clear liability conditions for technologies, pharmacies can use AI in the absence of oversight precautions. Legislative reform is necessary to protect patients and maintain accountability through continuous improvement. As AI automation permeates the global pharmaceutical industry, Ghana's correspondingly updated pharmaceutical law will facilitate responsible innovation. While existing resources support fidelity in traditional practices, current technical research follows industry trends. Enhancing registration requirements, administrative regulations and the ability to review research to estimate AI would enable the Ghana Pharmacists Council to preemptively control the emerging tools. New control measures can also clarify liability mechanisms. The customized regulatory changes will reinforce the use of AI, which is an accepted ethical practice in the community and serve as a model for other progressive health sectors moving towards digital transformation. health sectors moving towards digital transformation.

6. Potential risks and liability issues with AI pharmacy systems

Artificial intelligence (AI) offers tremendous potential for efficiency for pharmaceutical systems but also carries risks related to accuracy, technical disruption and data security but it is understood that Ghana's Pharmacy Act of 1994 did not anticipate automation advancement or account for attendant monitoring considerations. Thus, there are differences in liability that require legal reconsideration.

7. Accuracy Limitations

Machine learning algorithms rely on high-quality data sets and statistical assumptions that by their nature allow for a small margin of error. However, data biases or poorly estimated models can lead to inappropriate conclusions. For the pharmacy, incorrect dosage calculations or inappropriate medication recommendations put patients at risk. Records worldwide. The UK National Health Service trialed an inappropriate sepsis screening system in 2016 that mismanaged and missed more than 90 cases in one hospital [19]. While AI tools are rapidly improving, accuracy remains flawed, especially when the underlying data model changes over time. If similar issues have arisen with equipment dispensing or automatically recommending medicines in Ghana, the current flawed AI advice will fall under the direct legal accountability mechanisms that the Drugs

Act happens it is backed up by the emphasis on human responsibility. However, the U.S. and EU guidelines advise that manufacturers have an obligation to disclose high-risk AI applications such as clinical decision support software [15]. Ghana could consider similar responsibilities shared between manufacturers and manufacturers. Failure to formally define quality or certification requirements leads to problems for patients from imperfect but unserved AI devices.

8. Technical Disruptions

During the initial phase of the AI system process, robust quality control practices are paramount to reduce software errors. However, unexpected new events or infrastructure issues can still corrupt stored procedure data or cause the service to shut down unexpectedly. In particular, automatic delivery devices may experience technical faults during mid-processing. Researchers caution that AI tools are also still vulnerable to adversarial hacks or input manipulation [18]. Without contingency protocols to maintain continuity and data integrity, vulnerable patients are at risk of loss if access is compromised, medications are administered incorrectly, or records are compromised missed in. Although existing regulations emphasize manual pharmacy layoff requirements, rapid AI-specific development Regulations can effectively mitigate technical risks. Automation facilities must demonstrate appropriate failure modes during preauthorization and inspection. Expanding infringement penalties to cover specific data protection could also trigger cybersecurity.

9. Data Privacy & Security

The sensitive nature of medical history calls for higher data protection standards for healthcare providers, including pharmacies. However, the massive data storage and reliance on cloud computing resources increases the privacy and security risks around AI-enabled healthcare technologies as the lack of properly structured or managed personal information can go outside or be used by internal personnel a. While the Ghana 2012 Data Protection Act establishes Commission oversight for local organizations processing personal data, new industry-specific AI safeguards will support governance in pharmacy operations (Data Protection Commission 2012) In form which remains as Ghana whose objective can be transformed [16].

10. Unclear Legal Liability

While the manual practice emphasis of Ghana's Pharmacy Act enabled past enforcement, sanctions channels for AI-based errors remain undefined. Beyond privacy breaches falling under general data protection authorities, limited legislative precedence exists to guide civil or criminal proceedings following harm from automation utilization in pharmacy environments specifically. If AI performance contributed to adverse patient impacts, should manufacturers face product liability claims? Are operators solely accountable or would liability amicably diffuse across relevant stakeholders? Jurisdictional variability on AI governance globally compounds legal uncertainty [17]. As automation advances in Ghana's health sector, resolving such questions through legislative reform or test cases would boost industry confidence in new technologies. In summary, while AI automation promises immense benefits, Ghana's pharmacy oversight framework remains ill-equipped to address attendant risks. Amending current policy to mandate safety thresholds, resilience testing and usage qualifications for AI systems would enable more rigorous quality control. Similarly, clarifying liability channels regarding automation would shore up accountability as pharmacy progresses. Tailoring existing laws to emerging tools is key to balancing innovation with responsible regulation locally.

4. RECOMMENDATIONS

These are recommendations for regulations and oversight of AI pharmacy systems in Ghana focused on quality assurance, validation, transparency, liability updates and auditing review boards:

1. Quality Assurance

Data-driven AI model performance depends heavily on training inputs. As such, the international community proposed mandating data hygiene assessments so underlying datasets align with operational use cases regarding patient groups and variables (OECD 2019). Codifying similar data reviews as a registration prerequisite would verify representativeness before Ghana’s Pharmacy Council approved live testing or final AI pharmacy deployment. Implementing additional checks like simulation testing with demographic test groups could further validate intended functionality after data screening. Tying legal permissions to rigorous quality benchmarks tailored for automation would ensure responsible oversight keeps pace with advances.

2. Validation Protocols

While Ghana’s law currently lacks mandated reviews of automated technologies, international guidance stresses pre-and post-market surveillance to catch issues early [20]. Revisions to pharmacy registration rules could require facilities prove internal and third-party functionality assessments of all automation before granting AI usage permits. Enhanced active monitoring of model performance post-deployment would also allow rapid response to any accuracy deterioration over time through mandated external audits and transparent public reporting procedures around key benchmarks.

3. Transparency & Explainability

To supplement data validation, the global community also advises healthcare AI providers improve certain aspects of algorithm transparency so external auditors can better understand model outputs (OECD 2019). While full disclosure of proprietary code may not prove feasible, explanations of core logic, intended optimizations and limitations would empower auditing agencies (Mensah et al., 2023). Codes of practice surrounding data processing could also detail de-identification procedures and access policies to ease privacy concerns. Although Ghana's Data Protection Act establishes separate commission oversight, reinforcing transparency in sector-specific law would further strengthen accountability.

4. Updating Liability Laws

With AI, blame for negative patient impact extends to more people. Professionals creating equipment carelessly, employees using high-risk systems that lack control or data providers allowing biased input can all lead to injury in the form of a incorrect Thus, some jurisdictions mandate that manufacturers are liable for serious design defects inherent in algorithms sold for clinical use (European Commission 2021). s faces responsibility whether or not appropriate training is implemented . A clear definition of the mechanisms of qualified liability in Ghanaian legislation specific to self-service pharmacies would provide greater legal clarity.

5. Review Boards

Currently, the Ghana Medical Council conducts a lot of manual inspections and regulatory processes. While existing systems can handle minor changes, advanced automation governance is better suited to dedicated capabilities. Ghana could follow other countries and set up an independent review board of engineering, legal and medical experts to decide on applications for registration of pharmacies and audits on the implementation of AI systems [17]. In addition to active research and oversight, the advisory body may publish guidance on emerging issues governance. Overall research collected will enable appropriate policy development as automated pharmacies evolve. In summary, applying both precautionary limits and proactive audits creates an equally spread responsibility for AI risk among stakeholders If systematic reviews and sector-specific measures are organized clarifying the emerging responsibilities to strengthen the governance of the Ghana Pharmaceutical Authority in line with global AI governance developments. Regulatory frameworks designed to handle modern equipment drive innovation and responsible regulation as pharmacies slowly roll out across the country.

5. CONCLUSIONS

This study examined the shortcomings of the Pharmacy Act of 1994 in Ghana in terms of governance of emerging AI automation. As algorithmic devices and robotic delivery systems infiltrate pharmacy operations worldwide, the associated risks call for oversight strategies that balance innovation and prudence but current regulations does not eliminate quality control, pre-certification requirements, and liability mechanisms appropriate to modern technologies. The paper examined the gaps in registration requirements, practice standards, reviews and enforcement mechanisms in the regulation of artificial intelligence used in pharmacies. The mandatory unchecked automated system enables document less deployment and prevents the monitoring of recommendations or possible technical issues. Undefined liability mechanisms following AI-related errors also create legal uncertainty. Suggestions for addressing such gaps include the use of performance testing, transparent observation systems and dedicated review boards. Establishing accreditation criteria for responsible AI according to healthcare contexts would allow for tighter sector-specific surveillance. Revising the legislation to prevent the use of high risk to require an external audit without evidence of audit would also encourage accountability for progress. Regulation often lags behind in technical ways, but governance shows public confidence in emerging tools. While automated pharmacies stand to revolutionize access to and quality of health care, the rapid regulatory evolution of modern capabilities unlocks benefits in a sustainable way and it also supports patient safety. Updating decades-old policies prevents regulatory pressures that allow irresponsible use of information to proliferate until stricter limits become apparent. Instead, Ghana has the opportunity to take the lead in a sensible AI consent regime. By developing proactive strategies to capture efficiencies, ensuring transparency and limiting liability risks, policymakers can more rapidly sustain both innovation and oversight in the healthcare sector automation Regulatory reforms and the creation of regulatory powers for emerging technologies establish broad accountability accuracy. As algorithms shape lives, ensuring system governance policies match pace of development preserves the quality and reliability necessary for social acceptance.

Funding

No grant or sponsorship is mentioned in the paper, suggesting that the author received no financial assistance.

Conflicts Of Interest

The paper states that the author has no financial or non-financial interests that could be perceived as influencing the research or its interpretation.

Acknowledgment

The author extends gratitude to the institution for fostering a collaborative atmosphere that enhanced the quality of this research.

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