

AI-Driven Compliance and Risk Governance in Pharmacy Practice

Sharifah Norzehan Bt Syed Yusuf*

Accounting Research Institute, Universiti Teknologi MARA, Malaysia

Yuslina Binti Zakaria

Faculty of Pharmacy, Universiti Teknologi MARA, Malaysia

Intan Salwani Binti Mohamed

Faculty of Accountancy, Universiti Teknologi MARA, Malaysia

Md. Mamun Mia

Daffodil International University, Dhaka, Bangladesh

DOI Link: <http://dx.doi.org/10.6007/IJARBSS/v15-i9/26611>

Published Date: 28 September 2025

Abstract

The integration of artificial intelligence (AI) into pharmacy governance offers transformative potential to strengthen compliance, enhance risk detection, and reinforce ethical safeguards in healthcare systems. This paper examines how AI-driven tools ranging from automated compliance audits to predictive analytics for fraud detection can be harnessed to improve regulatory oversight in pharmacy practice. Drawing on governance and risk management theories, the study synthesizes existing literature on AI applications in healthcare, evaluates alignment with international frameworks such as ISO/IEC 38500, COSO-ERM, and the WHO Good Governance for Medicines, and proposes a conceptual AI-Integrated Pharmacy Governance Framework. The model emphasizes compliance monitoring, risk governance, and ethical accountability to address emerging challenges such as patient data privacy and transparency. By advancing a structured governance model, this paper highlights AI's capacity to balance innovation with regulatory rigor, offering pathways toward more accountable, efficient, and trustworthy pharmacy systems.

Keywords: AI-Driven, Compliance and Risk Governance, Practice

Introduction

Pharmacy practice sits at the nexus of healthcare delivery, patient safety, and regulatory oversight. Increasingly complex pharmaceutical ecosystems involving drug development, supply chains, prescription practices, and patient data management present significant governance challenges. Conventional compliance frameworks, reliant on manual audits and

reactive interventions, often lag behind the dynamic realities of modern pharmaceutical operations.

Artificial intelligence (AI) offers a transformative avenue to embed real-time monitoring, predictive analytics, and automated compliance into pharmacy governance models. AI-driven compliance systems can detect anomalies in prescription patterns, flag potential over-prescription of controlled substances, and monitor pharmacovigilance data to anticipate adverse events. By aligning AI applications with established governance codes such as ISO/IEC 38500 (IT governance), COSO-ERM (enterprise risk management), and the WHO Good Governance for Medicines framework, pharmacies can move towards a model that is both technologically advanced and ethically sound.

The integration of artificial intelligence (AI) and automatic learning (ML) in the practice of the pharmacy represents a transformative change in the way in which compliance and risk governance are addressed in the health sector. As regulatory environments are becoming more and more complex, the ability to navigate these challenges is essential to ensure patient safety and maintain adherence to regulatory standards. AI-centred compliance systems facilitate a proactive approach to managing regulatory requirements, allowing pharmacy professionals to rationalise workflows and offer superior patient care. The adoption of such technologies can lead to an improvement in operational efficiency, which reduces the risk of errors that could compromise patient safety.

Research highlights the compatibility of AI technologies with compliance executives. According to Ajmal et al. (2025), the incorporation of AI into regulatory cases can optimize examination and monitoring processes, while pharmacies remain in accordance with developing regulations. This technological progression allows faster response times to regulatory updates and emerging compliance problems, ultimately protecting patients by reducing the probability of surveillance. By taking advantage of the AI capacity for data processing and model recognition, pharmacy practices can develop predictive models that identify potential risks before they degenerate, allowing timely interventions that support patient safety.

In addition, synergy between AI and established governance executives is essential to create a culture of resilient compliance within the practice of pharmacy. As Gode & Gude (2024) point out, the alignment of AI capacities with regulatory guidelines strengthens the robustness of governance structures. This alignment is essential to promote an environment where compliance is considered not only as a check box exercise but as a full component of patient safety. Using AI-led tools, regulatory compliance becomes a continuous process informed by real-time data, allowing pharmacy professionals to adapt to new directives and requirements with agility and precision.

The data analysis capacities offered by AI add another layer of depth to governance in the practice of pharmacy. Chianumba et al. (2024) point out that improved data analysis improves compliance not only but also increases corporate governance standards. By using large volumes of data, AI can provide an overview of operational trends and risk of compliance, allowing pharmacy managers to make informed decisions that align with ethical standards and patient care. This analytical intelligence is reflected in exploitable strategies which

strengthen regulatory membership while promoting a safety culture within pharmacy operations.

By taking up the challenges posed by the evolution of regulations and requests for compliance, the implementation of compliance and governance of risk focused on AI is not without obstacles. Data confidentiality problems, the need for adequate training and the integration of AI into existing workflows require special attention. However, the potential advantages that these technologies offer in improving patient safety and regulatory compliance position them as critical tools for the practice of modern pharmacy. By aligning technological progress with established governance executives, pharmacies can overcome these challenges, paving the way for a safer and more efficient health system., The integration of the technologies promoted by AI in the practice of the pharmacy presents multiple challenges that must be carefully handled to guarantee alignment with the established governance frames. While AI's potential to improve patient safety and regulatory adherence is substantial, practical implementation realities cause concerns that cannot be overlooked. One of the main challenges is the problem of data privacy. The collection and use of patient data are fundamental for the functionality of AI systems; However, this raises critical questions regarding the protection of confidential health information. Adherence to data protection regulations, such as the Portability and Responsibility Law of Health Insurance (HIPAA) in the United States, requires solid government mechanisms to ensure that IA applications do not infringe the rights of patients or compromise confidentiality.

Pasas-Farmer and Jain (2025) highlight the importance of a comprehensive governance strategy adapted to the specific needs of AI technologies within the pharmaceutical sector. This strategy is essential to mitigate the risks associated with data management and algorithmic biases, thus promoting confidence between health professionals and patients equally. In addition, as Barbieri et al. (2025) examine the role of AI in the context of the management of the pharmacovigilance signal, they underline the urgency to develop sufficient governance frames. These frames are vital to take advantage of the AI ability to improve security measures while guaranteeing that the regulations that govern the safety and effectiveness of medicines are followed.

The rapid evolution of technology requires that the governance models of the pharmacy practice also adapt and transform. Glaser and Littlebury (2024) stress that existing governance structures are often poorly equipped to address the complexities introduced by advanced AI systems. There is a growing recognition that the principles that guide these frames should evolve to maintain the rhythm of technological innovations, which makes agility in governance a critical requirement for success. This evolution includes reviewing fundamental principles of regulatory practices and modifying them to account for the unique characteristics of AI, such as predictive analysis and real-time decision making.

Majakodunmi (2025) demands a robust reinforcement of the Mechanisms for Safety and Public Health Surveillance of drugs to involve AI solutions within a safety network that prioritizes the patient's well-being. The challenge, therefore, lies not only in the implementation of innovative technologies but also in ensuring that they are integrated into a comprehensive supervision panorama. Achieving this balance requires a proactive

approach, which allows interested parties to navigate complexities while they remain firm in their commitment to patient safety.

The general objective is to cultivate a culture of innovation that does not incur the cost of regulatory compliance or ethical considerations. The continuous dialogue between regulators, pharmacists, data scientists and policy formulators will be essential to shape the governance frames that can adapt flexibly to the new challenges while safeguarding public health. Therefore, as the practice of the pharmacy incorporates more and more technologies promoted by AI, addressing these challenges with an approach to collaborative and integral governance will be essential to take advantage of the benefits of innovation while guaranteeing patient safety and adherence to regulatory mandates.

Problem Statement

The integration of artificial intelligence (AI) in the practice of the pharmacy presents a transformative opportunity to address critical challenges, such as compliance inefficiencies, governance risks, pharmacovigilance limitations and ethical dilemmas. Despite these potential benefits, an integral governance framework is necessary to ensure that these technologies are integrated in a responsible and effectively integrated. Current practices often fall short in the management of complexities and nuances associated with the rapid evolution of AI capacities in medical care environments (Saha and Okmen, 2025). Therefore, establishing a cohesive government framework that covers all aspects of pharmacy practice is essential to safeguard these challenges.

Compliance inefficiencies remain a perennial problem within the practice of pharmacy, since rigid regulatory structures often hinder the adoption of innovative technologies such as AI. By adopting a governance framework that emphasizes adaptability and agility, pharmacy professionals can ensure that compliance requirements are not only met but also simplify through intelligent systems (Abdelmonem et al., 2025). The integration of AI can facilitate monitoring and real-time reports, thus improving regulatory compliance and reducing administrative load for pharmacists. However, without a solid government framework, the potential of AI to create more confusion and inefficiencies increases, endangering patient safety and the effectiveness of medicines.

The risks of governance also intensify with the integration of AI in the practice of the pharmacy. The lack of predefined standards and protocols can lead to an inconsistency in the application of AI, creating vulnerability to misuse or errors in the decision-making process (Jaibhagvan, 2025). An effective government framework must include clear guidelines that delineate responsibilities, establish supervision mechanisms and encourage transparency throughout the AI implementation process. In doing so, the practice of the pharmacy can mitigate the risks of governance, thus reinforcing the confidence of the interested parties and improving the credibility of the solutions of AI in the management of pharmacovigilance activities.

Pharmacovigilance limitations are particularly worrisome in the light of increasing the complexities of medicines and the increase in new treatment modalities. Traditional systems often struggle to capture adverse reactions to medications effectively, which makes it crucial that pharmacy practices take advantage of AI capacities to improve analysis and data reports

(MELO, 2024). A comprehensive governance framework must prioritize the integration of AI technologies to better manage pharmacovigilance efforts, ensuring that potential risks are identified and addressed proactively. This requires multidisciplinary collaboration among pharmacists, data scientists and regulatory agencies to build a receptive system capable of adapting to the dynamic nature of pharmacovigilance.

In addition, the ethical dilemmas surrounding the integration of AI in the practice of the pharmacy cannot be overlooked. Problems such as algorithmic bias, data privacy and dehumanization potential have significant challenges (Saha and Okmen, 2025). A governance framework must incorporate ethical considerations in its structure, ensuring that IA implementations maintain principles of equity, responsibility and transparency. When addressing these ethical dilemmas, the practice of the pharmacy can promote an environment of trust and safety, ultimately improving the results of the patients and defending the integrity of the profession.

The importance of an integral governance framework is further underlines for the need for continuous education and training. As IA technologies evolve, the pharmacy's workforce must remain informed about the best practices and regulatory changes (Szalonka et al., 2025). An integrated governance frame can provide a structured approach to professional development, ensuring that pharmacists and pharmacy technicians are properly equipped to use AI tools while adhere to ethical and regulatory standards.

In conclusion, the integration of AI in the practice of the pharmacy presents a series of opportunities and challenges that require a comprehensive governance framework. This framework must address compliance inefficiencies, governance risks, pharmacovigilance limitations and ethical dilemmas to maximize the benefits of AI integration. By promoting collaboration between interested parties and establishing clear guidelines, pharmacy practice can improve patient safety, promote ethical decision making and improve the general results for medical care. As the landscape of the pharmacy continues to evolve, prioritize a robust government framework will be essential to take advantage of the potential of AI while safeguarding the integrity and effectiveness of pharmaceutical care. Without these efforts, the pharmacy profession runs the risk of diving into inherited compliance challenges that AI has the potential to resolve, which prevents progress towards more effective and efficient health solutions (Abdelmonem et al., 2025; Jaibhagvan, 2025; Melo, 2024; Saha and Okmen, 2025; Szalonka et al., 2025).

Objectives

This paper seeks to examine the ways in which artificial intelligence (AI) technologies can enhance compliance systems in pharmacy operations, particularly through the use of automation and predictive analytics. By integrating AI into routine processes such as auditing, monitoring, and anomaly detection, pharmacy institutions can strengthen their ability to uphold regulatory standards, prevent malpractice, and ensure patient safety.

In addition, the paper aims to propose a governance model that aligns AI integration with established international standards, including ISO/IEC 38500 for IT governance, COSO-ERM for enterprise risk management, and the World Health Organization's Good Governance for Pharmacy framework. This alignment is intended to ensure that the deployment of AI in

pharmacy practice not only improves efficiency and oversight but also adheres to globally recognized principles of accountability, transparency, and ethical responsibility.

Literature Review

Theoretical Foundations of Governance and Risk in Pharmacy

The theoretical bases of governance and risk in the pharmacy are fundamental to guarantee the effective responsibility and management of risks in pharmaceutical practice. Historically, the commitment to maintain compliance with government regulations constituted the foundation of governance in the sector. Jagun (2018) places that adherence to regulatory paintings does not guarantee only compliance, but also promotes the trust between pharmacists, regulatory bodies and public. This perspective is particularly important in that the sector witnesses the rapid evolution of practices and the potential integration of innovative technologies, including artificial intelligence (AI).

Another key aspect of governance in the pharmacy is the relationship with the corporate government and the strengthening of pharmaceutical services. Chianumba et al. (2024) They argue that exploiting data analysis in the framework of the corporate government can significantly improve pharmaceutical practices, guaranteeing a more transparent and responsible system. Using data analysis, the interested parties can identify their roles and responsibilities, thus aligning with the expectations established in the regulatory paintings. This strictly aligns with the idea that effective risk management implies not only monitoring, but also the embrace of systems that encourage proactive compliance with regulations.

The concept of innovative regulatory paintings, as discussed by Langaro (2020), is particularly relevant in an era marked by the growing complexity in pharmaceutical services. Governance structures must evolve next to these paintings to adapt to new challenges. Langaro underlines that regulatory innovation is necessary to effectively deal with emerging risks in the practice of the pharmacy. Since traditional regulatory approaches may not be sufficient, governance progress requires a flexible and far -sighted mentality that embraces change and seeks new methods for the mitigation of risk.

Effective risk management, as articulated by Bais and Rathod (2024), includes a wider spectrum than conformity only; It implies a systematic approach to identification, analysis and risk resolution in the pharmaceutical sector. These authors underline that quality risk management should integrate both regulatory compliance and operational effectiveness, ensuring that patient safety remains central for pharmaceutical governance. Generally, risks management strategies must recognize the unique operational challenges addressed by pharmacies, at the same time adhering to consolidated regulatory paintings.

The integration of the theory of systems in the law on compliance, as suggested by Orozco (2019), represents a critical evolution in governance models in the pharmacy. This approach underlines the interconnection of various components of the pharmacy practice, suggesting that compliance is not simply an exercise in the control box but a global system that requires alignment of policies, practices and behaviors of the interested parties. The theory of Orozco systems underlines that the risks in the pharmacy are often systemic, which require a holistic approach to governance that emphasizes the responsibility and continuous evaluation of the effectiveness of compliance.

Understanding human factors behind the security problems of drugs in community pharmacies is essential for effective governance. To Juffali et al. (2019) They employed the framework of human factors to analyze the origins of drug errors, revealing that many accidents occur not due to clear negligence but rather due to systemic issues within the practice of the pharmacy. This intuition underlines the importance of integrating human factors into risk management strategies, supporting a responsible system that not only prescribes compliance, but also facilitates bankruptcy for the best safety results.

A conceptual picture established by Bader et al. (2017) highlights the various challenges to the progress of the pharmacy, providing a useful lens through which to understand governance and risk in the sector. Their work indicates different dimensions of the risk, including ethical considerations and the evolution role of pharmacists in patient care. This picture facilitates an analysis of the way in which governance models can be designed to navigate in the multifaceted panorama of the pharmacy, addressing issues of responsibility while incorporating risks management practices in daily operations.

The theoretical basis of governance and risk in the pharmacy has developed through historical commitments for regulatory compliance, innovative practices and a recognition of the importance of human factors in safety. Literature suggests that effective governance involves a multidimensional approach, incorporating data analysis to improve responsibility and compliance, systemic analyzes to deal with the ongoing risks and the development of complete framework that support the management of quality risk. Before the integration of artificial intelligence in practice it becomes predominant, establishing solid governance structures remains fundamental for the navigation of the risks inherent in the pharmacy. These framework will not only support compliance, but will also present themselves to the agile adjustments necessary in response to future challenges in an increasingly complex healthcare panorama.

AI Applications in Healthcare and Pharmacy Practice

The transforming role of artificial intelligence (AI) into medical care and pharmacy has become increasingly a focal point in recent years, especially in terms of crucial areas such as compliance monitoring, pharmacovigilance and predictive analysis. These applications not only improve the safety of medicines and risk management, but also pave the way for a more efficient health provision system. Through an integral examination of existing literature, this review clarifies how the AI reformulates these fundamental aspects of pharmacy and medical care.

One of the most shocking applications of AI is pharmacovigilance, a critical area to guarantee the safety of medicines and the management of risks associated with pharmaceutical products. The AI capacity to process large amounts of real-time data is to revolutionize how adverse events are monitored and managed. According to Shamim et al. (2024), the integration of AI with Big Data technologies allows a more significant idea about patient safety, which allows medical care providers to detect possible problems related to the medication before what traditional methods would allow. This proactive approach to pharmacovigilance ensures that patient safety remains at the forefront of medication administration practices.

Nagar, Gobburu and Chakravarty (2025) highlight the regulatory implications of adopting AI technologies in pharmacovigilance. By improving the monitoring of the safety of medicines through automation and advanced algorithms, AI systems can identify and inform efficiently adverse reactions to the drug, thus simplifying the regulatory process. This efficiency not only helps professionals to adhere to compliance standards, but also accelerates the time it takes to regulatory agencies to respond to possible security concerns.

The impact of AI also extends to compliance monitoring, where its application helps health centers to maintain regulatory standards. Kodali (2019) points out that automatic learning models are developing specifically for real-time pharmacovigilance. These automated systems can significantly reduce manual workload associated with compliance monitoring, thus minimizing human error. By automating data collection and reports, AI ensures that medical care providers can maintain compliance with regulations more effectively.

In addition, the role of AI in predictive analysis has attracted significant attention in recent studies. Predictive Analytics uses historical and real-time data to forecast possible drug adverse events. According to Potter and Karl (2023), automatic learning algorithms can analyze various data sources to predict which patients have a higher risk of adverse effects and create custom monitoring plans. This directed approach not only improves patient safety, but also optimizes the use of medical care resources.

Literature also emphasizes the future potential of AI in pharmacovigilance, as described by Ahire et al. (2024). Current trends indicate a growing will to adopt AI technologies for advanced monitoring and risk assessment. As AI continues to evolve, it promises to provide even more sophisticated tools to handle the safety of medicines, potentially integrating characteristics such as natural language processing to analyze unstructured data from social networks, patient reviews and clinical notes. These innovations can lead to richer data sets that improve the accuracy of the detection of adverse events.

Majakodunmi (2025) argues that the strengthening of public health surveillance through Pharmacovigilance promoted by AI presents the opportunity to improve the general results of medical care in communities. The systemic integration of AI can lead to more proactive health interventions, improving not only the safety of medicines but also public health on a broader scale. As IA tools improve our understanding of medicines interactions and patient responses, health professionals can devise more personalized treatment plans, which finally leads to better patient care.

Shukla et al. (2024) underline the importance of developing comprehensive frameworks to guarantee ethically responsible use in pharmacovigilance. As the AI dependence grows, it becomes increasingly vital to address the regulatory and ethical challenges that arise from use, ensuring that the systems remain transparent and responsible. The ethical use of AI in the monitoring and collection of data not only retains the privacy of the patient, but also encourages confidence in the health system.

AI applications in medical care and pharmacy are revolutionizing pharmacovigilance, compliance monitoring and predictive analysis. By improving the safety of medicines and risk management through real-time data processing, predictive automation and ideas, AI

promises to transform the way health professionals monitor the use of medicines and patient safety. As literature suggests, a concerted effort to adopt AI technologies, while adding ethical considerations, can result in a more effective and reliable health system, ultimately, benefits the results of patients and public health. Continuous advances in this field mean a new era of medical care where AI plays an indispensable role in guaranteeing security and compliance.

Ethical, Governance, and Policy Perspectives on AI Integration

The rapid integration of artificial intelligence (AI) in pharmacy practices has generated significant ethical dilemmas and governance implications that justify an in-depth examination. The navigation of balance between innovation and responsibility requires solid political recommendations that guarantee transparency and compliance. This revision of literature articulates the emerging challenges within the ethical panorama of the AI in the pharmacy, drawing on various academic contributions that highlight the need for global governance paintings.

One of the primary ethical dilemmas surrounding the IA in the pharmacy involves an algorithmic prejudice, which can perpetuate the disparities in the care of patients. Bahangulu and Berko (2025) point out that algorithmic distortion takes root in artificial intelligence systems through the training and model hypotheses data, leading to results that could disinfack some patient populations. In the pharmacy, in which decisions relating to drug prices, accessibility and therapeutic recommendations are critical, unjusted prejudice could strengthen inequalities. This underlines the need for established guidelines that impose a representation of different data and a continuous evaluation of artificial intelligence tools to guarantee equity and compliance (Bahangulu & Berko, 2025).

The Governance implications extend to transparency and responsibility in decision-making processes. The WHO (2021) outlines that the Ethics of the AI's governance must include mechanisms that guarantee the explainability of the results of the AI, in particular in the support systems for clinical decisions. For pharmacy professionals, relying on the AI-based recommendations requires a clear understanding of how these algorithms derive their suggestions. By implementing policies that impose transparent algorithmic processes, the interested parties can encourage trust between pharmacists and patients, thus improving the models of collaborative treatments.

Furthermore, the responsibility for the ethical use of the AI is significantly with healthcare professionals, who must be equipped to interpret the intuitions generated by the AI in a judicious way. Hasan et al. (2024) They underline that the implementation of the AI in the practice of the pharmacy raises ethical considerations relating to the responsibility of professionals and the autonomy of the patient. Since pharmacists depend more and more on artificial intelligence tools for the decision-making process, a passage to education and continuous training becomes essential. These initiatives can prepare pharmacists to critically evaluate the actions recommended by artificial intelligence, thus maintaining responsibility for the care of patients.

In addition, there is an urgent need for global political recommendations that face governance challenges inherent in the application of the AI in the pharmaceutical sector. Hakimi et al. (2024) propose the establishment of interdisciplinary committees that include politicians,

health and ethical operators to formulate reactive governance structures. These committees would be decisive in the elaboration of the guidelines that align technological innovation with ethical standards, ensuring that patient safety remains fundamental in the AI applications.

The challenge of integrating the IA effectively in the practice of the pharmacy also includes pharmacovigilance, where continuous monitoring of drugs safety is vital. Saha and Okmen (2025) say that the IA has the potential to revolutionize pharmacovigilance practices, but unregulated use could lead to ethical issues relating to data privacy and informed consent. To respond to these concerns, policies that regulate access to the sensitive information of the patient should be developed, outlining clear protocols on how the data should be used and shared. Sturdy privacy protections can help safeguard patient rights, balancing the benefits of AI with the risk of improper use of data.

At the same time, the ethical implications of the AI in the pharmacy go beyond individual practice to understand wider social considerations. Singhal et al. (2024) provide a discovery revision that identifies the interaction between the Ethics of the AI and determinants of public health, illustrating the wider implications of the governance paintings. Politicians must interact with these ethical discussions, considering how artificial intelligence applications could inadvertently model the results of health between different demographic groups. Therefore, promoting public discourse on the IS implications within the pharmacy could help create more inclusive political paintings.

Enhancing the governance of the AI is essential for the ethical boundaries pioneers in the practice of the pharmacy. Ravali Et Al. (2023) support the establishment of supervision bodies capable of monitoring and evaluating the ethical trajectories of the AI in health care. These entities would play a crucial role in validating artificial intelligence systems against pre-established ethical benchmarks, conducting ongoing assessments to mitigate the potential damage associated with artificial intelligence applications. This supervision can ensure that innovation does not eclipse the ethical principles that guide the practice of the pharmacy.

Since the IA continues to remodel the practice of the pharmacy, facing ethical dilemmas and governance implications is of the utmost importance. The implementation of political recommendations that emphasize responsibility, transparency and compliance will be fundamental to navigate in the ethical panorama of the AI in the pharmacy. By promoting the interdisciplinary dialogue and by establishing solid governance paintings, the interested parties can guarantee that the integration of the AI serves to improve assistance to patients by supporting the ethical standards that give priority to equity and equity through the healthcare scene. As the evolution of the pharmacy continues to take place in the midst of technological progress, the need for resolution and ethical station will remain a milestone of responsible practice.

Methodology

Building on the insights established in the literature review, this study adopts a conceptual and normative research design grounded in governance and risk management theory. Conceptual research is especially suited for studies that seek to theorize and propose frameworks without empirical testing, as it allows for structured integration of existing theories and practices into new governance models (Creswell & Creswell, 2018). Since the

objective here is to advance a governance model rather than conduct field experimentation, the methodology emphasizes analytical synthesis and conceptual development over data collection. The purpose is to articulate how artificial intelligence (AI) can be systematically embedded into pharmacy governance frameworks to enhance compliance, risk oversight, and ethical accountability.

The first stage of this approach is a targeted literature synthesis. Scholarly works, regulatory guidelines, and policy documents are critically examined to identify existing uses of AI in healthcare, particularly in compliance automation, prescription monitoring, and pharmacovigilance. Special emphasis is placed on established international frameworks—ISO/IEC 38500 on IT governance (ISO, 2015), COSO-ERM on enterprise risk management (COSO, 2017), and the WHO Good Governance for Medicines initiative (World Health Organization, 2014) which provide normative benchmarks for evaluating pharmacy governance. By mapping these references, the review uncovers gaps in regulatory and oversight mechanisms where AI can deliver significant improvements.

The second stage centers on conceptual model development, leading to the AI-Integrated Pharmacy Governance Framework (see Figure 1). This framework is built on three interconnected pillars: compliance monitoring, risk detection and predictive analytics, and ethical safeguards. The compliance pillar illustrates how AI can automate audit trails, detect anomalies in prescription behavior, and support adherence to regulatory requirements. The risk detection pillar emphasizes predictive analytics to anticipate vulnerabilities such as fraud, over-prescription, or diversion of controlled substances. Finally, the ethical safeguards pillar underscores transparency, patient privacy, and professional accountability, ensuring that AI enhances governance without undermining human responsibility.

The final stage is the normative alignment of the model with global governance codes and ethical standards. This ensures that the proposed framework is not only theoretically robust but also practically adaptable for pharmacy institutions, regulators, and policymakers. By aligning AI's technical capacities with governance principles, the methodology provides a bridge between innovation and institutional responsibility.

Taken together, this methodology extends beyond description to propose a structured, theory-informed process that results in a forward-looking governance framework. By integrating literature insights, conceptual modeling, and normative benchmarks, the study ensures coherence with the broader discussion of AI-driven compliance and risk governance. This methodological foundation directly supports the subsequent analysis and conclusion, where the framework's implications for pharmacy practice and governance are further elaborated.

Finding Discussion

In recent years, the integration of Artificial Intelligence (AI) in various sectors has led to the need for a structured governance model that align with structures established as ISO/IEC 38500, COSO-ERM and which is a good governance for the pharmacy. This alignment is crucial to promoting an ethical, responsible and risk awareness methodology for AI implementation. The interaction of these structures provides a fundamental basis for addressing the complexities that arise with AI in a governance context.

The ISO/IEC standard 38500 emphasizes the importance of effective IT governance, focusing on principles such as responsibility, strategy and performance. To align AI integration with this structure, organizations must ensure that AI initiatives promote responsibility at all levels. A model that incorporates the supervision of the IAI project council with the ISO/IEC principles, ensuring that decision makers are fully informed about the implications of AI processes. Castellanos (2020) highlights the importance of IT governance in maintaining alignment between business objectives and technology initiatives. In applying these principles to AI governance, organizations can improve their strategic results, mitigating risks associated with AI implementation.

Meanwhile, the COSO-ERM structure provides an integrated risk management approach, which is crucial in considering the multifaceted risks that I present it, such as concerns about data privacy, bias in algorithms and potential misuse. A model of effective Governance for AI should leverage the principles of COSO - specifically, identifying and evaluating the risks associated with AI technologies. Organizations must develop a Risk AI management strategy that articulates the risks involved and integrates them into their general corporate risk management processes. This synergy between AI governance and COSO-EMR not only identifies operational risks, but also strengthens an organization's ability to respond to ethical concerns around AI implantations.

Returning to the good governance of WHO to the pharmacy, the emphasis is on the transparency, responsibility and involvement of stakeholders. For the integration of AI in the pharmacy sector, a governance model that incorporates these principles is essential. By ensuring transparency in AI algorithms, health professionals can build confidence with their patients who may be careful with automated systems. This aligns with the discoveries of Castellanos (2020) on the influence of IT governance on the alignment between business goals and IT. The integration of the perspectives of the stakeholders in the IA governance structure will help address community concerns, thus promoting a culture of ethical consideration in the heart of AI initiatives.

In addition, involvement with professional pharmacy organizations and regulatory agencies can improve governance models, ensuring that AI tools respect established ethical standards and contribute positively to health results. These partnerships can help create best practices and guidelines adapted to the unique challenges faced in the field of pharmacy by integrating AI. By creating a feedback cycle with these stakeholders, organizations can adapt their AI strategies and governance models to meet evolving ethical and regulatory landscapes.

The interconnection between ISO/IEC 38500, COSO-ERM and which is a good governance for the pharmacy provides a model of holistic governance that transcends traditional structures. Establishing a advice or committee dedicated to overseeing AI initiatives can serve as a practical implementation of this proposed governance model. This entity would be responsible for monitoring AI use, evaluating risks and ensuring compliance with ethical standards. By facilitating continuous education and training for employees on the principles of governance around AI, organizations can cultivate a risk aware culture that responds to ethical dilemmas.

In short, a governance model that effectively aligns AI integration with ISO/IEC 38500, COSO-ERM and which is a good governance for pharmacy, plays a key role in ensuring ethical implementation, responsible and risk awareness of AI technologies. Recognition of the contributions and prerequisites of each structure facilitates the development of a cohesive strategy that supports informed decision-making and the responsible use of AI. As organizations sail in this complex scenario, the integration of these principles of governance will help protect not only the interests of the organization, but also those of patients and the larger community, reflecting a commitment to ethical governance in the AI of AI.

AI-Driven Compliance and Risk Governance in Pharmacy Practice

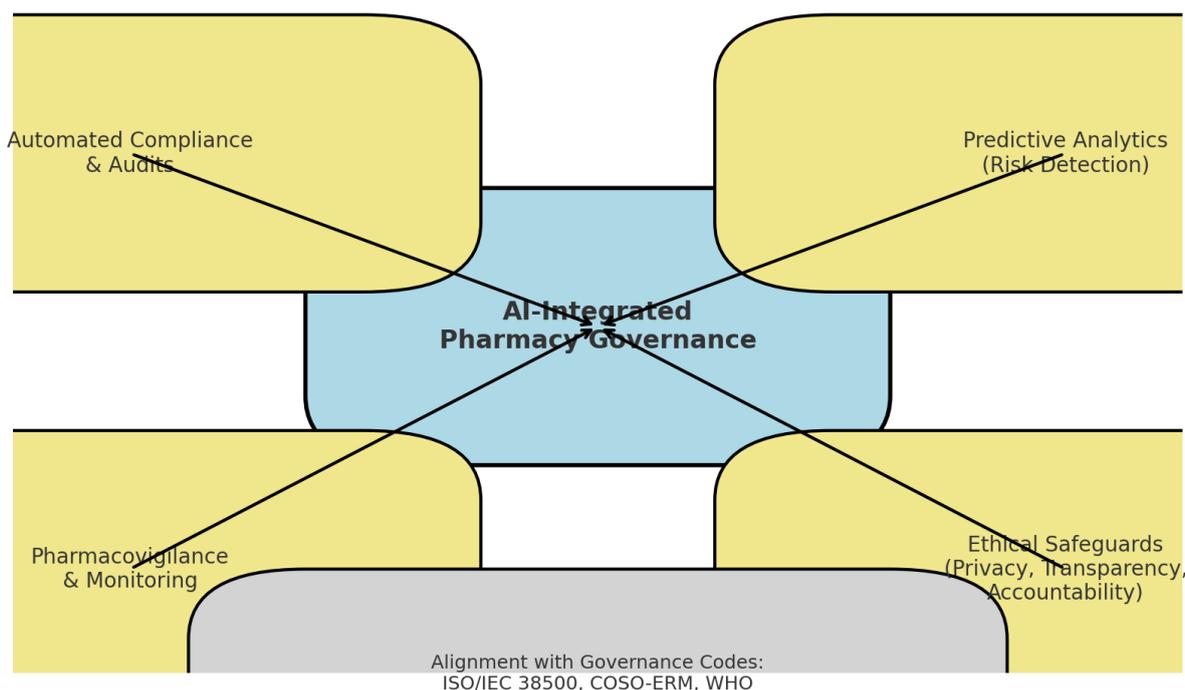


Figure 1: AI-Driven Compliance and Risk Governance in Pharmacy Practice

Figure 1 illustrates the proposed framework for integrating artificial intelligence into pharmacy governance. At the center of the model is the AI-Integrated Governance Core, which coordinates key functions such as compliance monitoring, risk detection, pharmacovigilance, and ethical safeguards. Surrounding this core are the operational components—automated audits, predictive analytics, and real-time monitoring—that enable pharmacies to transition from reactive oversight to proactive governance. By embedding these AI-driven functions into daily practice, the model highlights how technology can serve as both a compliance enabler and a risk management tool, ensuring accountability while strengthening patient safety.

Equally important, the framework underscores the need for alignment with internationally recognized governance standards such as ISO/IEC 38500, COSO-ERM, and the WHO Good Governance for Medicines. This alignment ensures that AI adoption does not merely focus on efficiency, but also adheres to established principles of transparency, ethical responsibility, and stakeholder engagement. In this way, the model moves beyond technical innovation to

emphasize sustainable governance structures that integrate human judgment, regulatory compliance, and technological capacity into a cohesive system for modern pharmacy practice.

Conclusion

The integration of artificial intelligence into pharmacy governance represents not merely a technological upgrade but a transformative shift in the ways compliance, risk, and ethical oversight are conceptualized and operationalized. AI can reshape healthcare compliance through automation, anomaly detection, and predictive analytics, reducing human error while improving efficiency (Jiang et al., 2017; Davenport & Kalakota, 2019). By embedding AI into compliance monitoring and pharmacovigilance, pharmacy institutions can move beyond reactive governance structures and develop proactive mechanisms that anticipate challenges, address inefficiencies, and reduce the likelihood of fraud or malpractice (Reddy & Sharma, 2020).

The proposed governance model highlights how AI can be systematically aligned with established international frameworks such as ISO/IEC 38500, COSO-ERM, and WHO's Good Governance for Medicines. These standards provide the scaffolding for ensuring that the adoption of AI is not only efficient but also responsible and ethical (ISO/IEC, 2015; COSO, 2017; WHO, 2014). Without transparency and accountability, the benefits of AI risk being overshadowed by data misuse, algorithmic bias, or opaque decision-making (Jobin et al., 2019). Thus, the model emphasizes balancing automation and predictive analytics with safeguards that preserve human judgment and ethical oversight.

The challenges identified particularly ethical dilemmas, patient trust, and regulatory adaptation underscore that the deployment of AI is not a panacea but a pathway requiring careful calibration. Policymakers, regulators, and professional bodies must define clear boundaries for AI use and ensure that compliance mechanisms remain adaptable to technological and social change (Zetzsche et al., 2020). In this sense, AI should not replace governance but rather enhance it by offering tools that expand institutional capacities for accountability and risk management.

The success of AI integration will ultimately depend on the governance culture of pharmacy institutions. An organization that embraces AI as a partner in decision-making, rather than a threat to professional autonomy, will better reap the benefits of foresight and efficiency. A culture of openness and ethical vigilance is essential for navigating trade-offs between innovation and integrity (Floridi & Cowls, 2019). From this perspective, several practical implications can be drawn: investment in AI-driven auditing platforms, regulatory adaptation, targeted training for pharmacists, and collaboration across institutions to establish shared ethical guidelines.

In conclusion, the AI-Integrated Pharmacy Governance Model provides a conceptual foundation for reimagining compliance and risk governance in pharmacy practice. By embedding AI into governance structures, pharmacies can strengthen their ability to meet regulatory obligations, manage risks proactively, and foster trust among stakeholders. If implemented thoughtfully, AI will not only optimize compliance and risk management but also elevate pharmacy governance in safeguarding patient welfare and public health. The future of pharmacy governance, therefore, lies not in resisting technological change, but in

Acknowledgement

The authors gratefully acknowledge the support of the Accounting Research Institute (HICoE), Universiti Teknologi MARA, and the Ministry of Higher Education Malaysia for facilitating this research.

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