

LEGAL AND REGULATORY READINESS FOR ARTIFICIAL INTELLIGENCE IN SAUDI ARABIA'S ORGAN TRANSPLANTATION SYSTEM: CHALLENGES, AND POLICY PATHWAYS

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Abstract

The increase in the use of artificial intelligence (AI) in the world of healthcare, has raised serious regulatory and ethical dilemmas particularly in the domain of organ transplantation. In Kingdom of Saudi Arabia (KSA), where both religious and legal and institutional standards control organ donation, AI allocation and decision-making present concerns regarding transparency, accountability and Shariah standards. Although the KSA have introduced programs like Vision 2030 and National Strategy of Data and Artificial Intelligence (NSDAI), but the legal frameworks of AI regulation in KSA is still in infancy. The paper follows a qualitative, desk-based, legal, and policy review based on the Regulatory Governance Theory (RGT) to evaluate the preparation of Saudi Arabia to integrate AI into the field of organ transplantation. It examines the domestic policies, documents, ethical guidelines and the international models of the United States, the United Kingdom, and the European Union. The study found serious gaps in algorithmic regulation, information management, and organizational capability. The results show that there is an immediate necessity of industry regulation, ethical audit frameworks, and inter-agency cooperation. The research suggests a culturally based system of governance, which will be consistent with the Islamic bioethics, social responsibility, and international best practices regarding AI implementation. It provides pragmatic suggestions to reform laws and the policy innovations, which facilitate the shift of KSA to ethical and technologically based organ transplantation systems.

1. INTRODUCTION

The concept of AI has quickly become a revolution in the healthcare system around the world, with a certain potential to enhance efficiency, accuracy of prediction, and decision-making in a range of medical fields. In organ transplantation, in particular, AI-based systems have demonstrated the possibility of establishing better donor-recipient matching, predicting the results of the post-transplant period, and simplifying the logistics (Pruinelli et al., 2025). In many countries, including the United States and the United Kingdom, AI has

started to be incorporated into transplant-related systems on a global basis as countries install quality ethical and regulatory frameworks (Yeung, 2018; UK Department of Health, 2021).

Digitization and adoption of AI are the driving force of the Vision 2030 agenda in KSA, where the National Strategy of Data and Artificial Intelligence (NSDAI) imply the plans to become the global AI leader (SDAIA, 2020). One of the areas that have been targeted in AI transformation is healthcare and most importantly organ transplantation. However,

even with such ambitions, there is still a large gap in the law and regulatory frameworks needed to regulate the application of AI in the sensitive medical areas. This involves the absence of industry-specific principles on the application of AI in the process of donating organs, such as ethical responsibility, data security, and transparency in algorithms.

Problem Statement

KSA is significantly investing in AI and digital health infrastructure, though the legal and regulatory systems in place currently fail to adequately consider the risk of AI in organ transplantation, which is unique. The current transplantation regulations are mostly silent regarding the impact of algorithm-based systems on allocation decisions, leaving regulatory gaps in data and liability management, as well as the Shariah-compliant areas (Solaiman et al., 2024). These legal ambiguities can cause ethical breaches, misdistributions, and loss of trust in the medical system and digital governance as AI starts to contribute to a higher role in medical decisions.

Significance of the Study

The research paper adds to the existing academic and policy discussions regarding AI regulation within critical healthcare contexts by offering a context-specific, legally based analysis of KSA. The available literature on AI is either generic or the study of organ transplantation concerning bioethical and religious issues, without discussing how they might converge on the regulation (Al-Bar and Chamsi-Pasha, 2015; Ghaly, 2018). This study addresses a knowledge gap in policy design and implementation because, using the Regulatory Governance Theory, it presents formal institutions, ethical norms, and technology in terms of their interaction (Levi-Faur, 2011).

Practically, this study will assist KSA policymakers, regulators, and medical practitioners to be able to develop AI integration paradigms, which are ethically defensible, legally reasonable and culturally consistent. It is also applicable to other countries of the Gulf Cooperation Council (GCC) that are considering such avenues towards AI adoption in the healthcare field. The study provides a contribution to the creation of the public trust, regulatory

legitimacy, and technological responsibility in the changing healthcare system in Saudi Arabia by revealing the governance dilemmas and offering legal solutions to the identified problems.

Research Questions

- What are the legal and regulatory gaps in KSA, as far as the use of AI in an organ transplantation is concerned?
- What international best practices are noticeable in the regulation of the use of AI in organ transplantation?
- What are the legal, ethical and institutional risks of applying AI in organ donation systems in KSA?
- What is the role of a regulatory governance system in influencing the legal and institutional preparedness of KSA in this field?

Research Objectives

- Examine the existing legal and institutional frameworks of AI, and organ transplantation in KSA.
- Determine loopholes in the current laws, ethical protection, and regulatory measures.
- Identify international systems of AI regulation in transplantation and derive insights on KSA.
- Suggest a regulatory governance structure that would fit in KSA cultural, legal and ethical environment.

Literature Review

The debate on the legal and regulatory aspects of organ transplantation in KSA has been dominated by the bioethical interpretation of the law and Islamic jurisprudential approaches. Al-Bar and Chamsi-Pasha (2015) help to establish a general concept of how Islamic bioethics is applied to the acceptability of organ donation, specifically, with the help of the principles of *maslahah* (public interest), *adl* (justice), and *niyyah* (intention). The present literature highlights the fact that organ donation in Saudi Arabia is closely coupled with the Shariah standards and institutional control via Saudi Center of Organ Transplantation (SCOT).

Nevertheless, the existing literature tends to believe that organ donation is a static ethical and medical dilemma that seldom considers the changes necessitated in technology that require the redefinition of the law. As an example, the analysis conducted by Al-Bar and Chamsi-Pasha (2015) does admit that innovation is ethically acceptable in cases where it saves life, but nothing is said about how the use of the algorithmic tools, especially in AI, might affect ethical decision-making in organ donations. An early gap can be denoted by the lack of discussion on the topic of automated matching systems, AI-assisted logistics or the algorithmic transparency of such Islamic bioethics literature that is the technological neutrality of the existing jurisprudential literature.

In the meantime, more recent policy-oriented sources, including that by Solaiman et al. (2024), have started to discuss the connection between the larger digital health goals pursued by KSA, and ethical and legal preparedness. The author believes that the legal frameworks of KSA are not keeping pace with its digital health environment, and thus, the ethical controls systems remain in their infancy. They specifically indicate that the disconnect between the National Strategy of Data and Artificial Intelligence is missing at SDAIA and in areas specific to the industry, such as organ transplantation, there are no specific laws to regulate the AI integration.

A comparison of this with international models sheds more light on the regulatory lag. The application of AI to the NHS Blood and Transplant system in UK is regulated within the framework of the NHSX AI Ethics Framework that establishes such principles as explainability, fairness, and auditability (UK Department of Health, 2021). In a similar manner, in the United States, the AI-based simulation tools developed by UNOS are publicly reported and under permanent review, which demonstrates the way, in which the legal and ethical transparency is embedded into the technological execution (Pruinelli et al., 2025).

The KSA literature of organ transplantation is quite abundant in ethical and religious commentary, but it does not contain this combination of governance discourse with technology. Most country regulations presuppose human decisions and do not mention who should be responsible when a machine decides

who is prioritized in the choices or the bias of an algorithm works against some groups of patients. This is not a mere omission; in terms of transplantation, such choices usually amount to life or death. The concept of algorithmic actors in the KSA regulatory literature being legally invisible is a significant gap in the topic.

Another notable fact is that the Vision 2030 of Saudi Arabia and NSDAI focus on the issue of AI-based healthcare transformation; however, these are not regulatory documents but strategic ones. The guidelines provided by SDAI are of high level, principle-based, and do not provide binding requirements in clinical or bioethical situations. They refer to the notions of fairness and explainability, but without health-specific implementation frameworks, implementation remains unclear (SDAIA, 2020). Thus, another debate is taking shape in the policy analysis community: should AI use in life-or-death choices such as organ transplantation be treated as medical technology, data machinery, or even a policy problem?

The strict laws of KSA in relation to human organ trafficking and consent are discussed by such legal theorists as Hegazy (2025), but even these studies fail to address the issue related to the use of digital tools to complicate the legal interpretation. As an illustration, in case an AI model distributes an organ wrongly or employs systematic bias, the existing law does not provide anything specific about the liability: is it the hospital, the developer, or the algorithm? These legal dilemmas are not currently addressed in the literature. This secrecy is an indication of a wider regulatory ambiguity over AI in KSA where AI is being encouraged but has yet to be fully embraced within the legal framework.

Simultaneously, researchers of the Islamic jurisprudence, such as Ghaly (2018), have discussed the possibility of accommodating biomedical innovations within Islamic law. He claims that innovations in ethics may be defended by *ijtihad* (autonomous thinking) and *istaisah* (national interest), particularly in the cases when human life is in danger. This paves the path to the integration of AI, yet the literature that translates this stream of thinking into practical application, i.e. into the relationship between Islamic ethics and algorithm

design, is still lagging. It is intellectually feasible, but empirically and legislatively immature, that a *Shariah* (Islamic Law)-compliant AI ethics framework could be applied to transplantation. Therefore, although certain literature views KSA organ transplantation in the context of religious morality and ethical setting of priorities, and other strands report on the possible readiness of AI in the abstract strategic sense, hardly any literature connects the two. There are critical implications of such a disconnect. In the absence of a cohesive discussion between religious ethics, legal requirements, and technological innovation, AI in transplantation will be stagnated due to ignorance or adopted blindly.

Lastly, the international AI ethics standards, including the ones provided by the WHO (2021) and European Commission (2021), provide more elaborate risk-based regulation, algorithmic auditing, and engagement frameworks. These are mentioned in KSA organ transplant policy literature as an objective to be achieved, but they are not framed with local cultural, legal, or institutional contexts. Consequently, efforts to shape the KSA organ transplant policy to international standards of AI cannot be wholly successful, unless they are remodelled to meet national standards.

Theoretical framework

The introduction of AI within the healthcare system, especially the provision of the technology on ethically sensitive services like organ transplantation, cannot be achieved only through technological preparedness but requires a multidimensional mode of governance. In this study, the researcher uses the Regulatory Governance Theory to conceptualize the legal and institutional difficulties that KSA encounters when developing an AI-ready organ transplantation system. Regulatory governance is concerned with how rules, institutions, norms, and the enforcement systems interact in the management of complex technological systems (Levi-Faur, 2011). It goes beyond classical command-and-control forms of regulation and focuses rather on how a nexus of state, market and societal forces is constituted to influence rulemaking, compliance and accountability.

With respect to KSA, organ transplantation is already so mediated by religion and centralized

medical control. Nevertheless, the fast development of AI raises new regulatory concerns, including accountability, transparency, fairness, and data protection of algorithms, which are not discussed in current legal regulations (Solaiman et al., 2024). Thus, the conceptual model applied in the current research suggests that the regulatory preparedness in KSA is a result of the interplay between four spheres, which include legal framework, institutional capability, ethical-religious control, and technological regulation.

Legal infrastructure is the presence and sufficiency of legal obligations that govern AI application in medical care and more specifically in organ transplant. Although SCOT regulates the process of organ allocation (according to clinical principles and in accordance with Islamic ethics), the legal statute that regulating AI implementation in this area is in place is not yet established (Hegazy, 2025). The lack of AI-specific legal tools leads to a grey area, in which AI-based decision-making can take place without a specific legal responsibility or procedural protection.

The second pillar is institutional capacity that entails the abilities of the organizations such as SDAIA, SCOT, and the Ministry of Health to align policies, introduce controls, and respond to new technologies. Although SDAIA has already established national ambitions with regard to AI by its National Strategy on Data and Artificial Intelligence, they are still strategic and not operational regarding health-specific sectors (SDAIA, 2020). Accordingly, the regulation of AI in organ transplantation is fraught with the lack of unity between health and technological regulatory authorities, which undermines the implementation of moral and legal norms.

The third factor is the importance of ethical and religious supervision. The Saudi health law is largely dominated by Islamic bioethics, which is based on such concepts as *maslahah* (public benefit) and *adl* (justice) (Al-Bar and Chamsi-Pasha, 2015). However, the modern religious discussion fails to address the ethical aspects of algorithmic decision-making. Although Islamic jurisprudence has been adaptable to the introduction of medical innovation (Ghaly, 2018), the institutionalized channel of *Shariah* scrutiny of AI systems, particularly those systems applied in critical allocation cases, is lacking.

Lastly, technological governance means that it has mechanisms in place, including algorithmic audits, data governance protocols, and explainability tools. The Saudi health ecosystem is mostly deficient of these. In contrast to the EU AI Act or the ethical principles of AI use in health developed by the WHO, KSA does not have any sector-specific AI governance principles (European Commission, 2021; WHO, 2021). In their absence, AI integration can be seen as the risk of undermining the population and moral integrity.

These domains are also interdependent when combined. Regulatory preparedness is not merely a legislative one but a coherence and coordination between institutions, norms and technical infrastructures. Basing the study on this framework enables the evaluation of the readiness of KSA to AI holistically in the field of transplantation, and find out where exactly policy, ethical reasoning, or law change is needed the most.

Methodology

The proposed study utilises a desk-based qualitative legal and policy analysis to review the regulatory and institutional preparedness of KSA to adopt the use of AI to the organ transplantation system in KSA. The normative and exploratory requirements of the research project are better addressed by the methodology since the research will not produce new empirical data, instead, it will make sense of the existing laws, ethical principles, institutional structures, and policy documents. In this way, a critical assessment of legal texts, national strategies, ethical standards, and religious decisions that affect or control AI use in the healthcare industry can be made.

The information will be gathered by accessing and cultural surveying the wider secondary sources such as peer-reviewed journal articles, governmental-released white papers, strategy documents on AI (including those released by the Saudi Data and AI Authority), governmental healthcare regulations, and scholarly texts on Islamic bioethics. Also, primary policy documents like the official organ transplantation policies of SCOT, laws in the field of healthcare and AI, and reference fatwas of the established Shariah bodies are examined.

In carrying out the study, qualitative content analysis is used to analyse data based on the principles of the regulatory governance theory. Themes that are coded in the legal texts and policy documents include accountability, algorithmic transparency, institutional roles, ethical safeguards and Shariah compliance. The interpretation and comparison are the interpretive and comparative type of analysis, and benchmarking of the practices of other global regulatory models can be made (e.g., the EU AI Act, WHO guidance, UNOS protocols). The sampling strategy used is purposive in which documents and literature used in the study are the most pertinent to the research questions and are as well pertinent to the context of the study.

Findings and Discussion

According to the Regulatory Governance Theory, the institution of high-risk technological systems, including AI in healthcare, is best governed through institutional coordination, legal requirements, ethical supervision, and adaptive capacity (Levi-Faur, 2011). The legal tools necessary to support the implementation of the National Strategy for Data and Artificial Intelligence (NSDAI) are either not developed or non-existent in KSA, although sector-specific legislation in the healthcare sector, is articulated (SDAIA, 2020).

The SCOT controls the organ donation and transplantation, guided by ethical values founded on Islamic law, and it includes human dignity, non-maleficence, and justice (Al-Bar and Chamsi-Pasha, 2015). Nevertheless, the policies are conventional in terms of physician-centered human-based decisions. As of now, there are no legal systems in place to specify or regulate the application of AI algorithms to donor-receiving matching, prioritization, or allocation. In KSA, the law on transplantation, which has been strong in its prohibitive approach to trafficking and ethical consent to the decision-making process, does not touch on the algorithm participation in the procedure (Hegazy, 2025).

This control gap is particularly acute when one is why AI systems may also impact life-and-death decisions. According to Regulatory Governance Theory, this type of technologies must be regulated legally to allow the creation of accountability and legitimacy (Yeung, 2018). However, in KSA, the

problems of liability, data protection, and the fairness of algorithms are not legally well-defined. As an illustration, when an AI system distributes an organ incorrectly because of discriminatory data or inadequate reasoning the law does not give us any idea as to whether the responsibility is on the hospital, developer, or regulatory agency.

The law of the Protection of Personal Data (PDPL) that came into effect in 2021 does not specifically cover the information about healthcare-related data when it comes to the AI-supported decision system (Solaiman et al., 2024). It is the opposite of the GDPR, which has provisions of automated decision-making and the right to explanation (European Commission, 2021). Although the law of KSA places a high value on privacy of data, there is no interpretative part when dealing with automated clinical judgments, especially in transplantation where the level of data sensitivity and ethical considerations is high.

Besides, KSA does not need impact assessment, algorithmic audit, or explainability requirements of AI systems used in healthcare at present. This compromises the main principles of regulatory governance, which prioritizes transparency and public accountability as measures to curb technocratic obscurity (Yeung, 2018; Levi-Faur, 2011). And because regulatory systems are not in place to audit AI systems prior to deployment, there is a high likelihood of becoming stuck in structural bias or ethically incorrect with no remedy.

Also, other religious oversight systems that have facilitated the transplantation practices, like Shariah committees, have not been incorporated in digital health governance. The Islamic scholars have ruled historically in favor of medical innovation in the context of such principles as *maslahah* (public benefit), but there has never been an institutionalized approach to scrutinize AI tools in the Shariah context (Ghaly, 2018). Such a lack of connection undermines trust in the population and puts the adoption of AI in ethically ambiguous sectors in question.

Therefore, institutional silos, legal ambiguity, and normative fragmentation are visible in the Saudi regulatory framework nowadays, and they prevent the responsible implementation of AI in organ transplantation. Regulatory governance is a fantasy

without specific legislative change and mechanisms of cross-sectoral governance.

Based on the world experience of regulatory governance, KSA can learn a lot of valuable lessons with references to the countries that have already developed AI into their systems of organ transplants under a strict ethical and legal control. In the United States, United Network for Organ Sharing (UNOS) uses artificial intelligence simulations and data analytics packages, such as LSAM (Liver Simulated Allocation Model) to aid organ allocation, however. The tools are subject to multidisciplinary oversight boards, which is why they are not only valid in clinical terms but also equitable (Pruinelli et al., 2025). The legal system of the United States recognizes some types of AI-driven systems as Software as a Medical Device (SaMD) and makes them undergo pre-market approval, post-market surveillance, and clinical validation (FDA, 2021). Most importantly, UNOS systems do not eliminate human-in-the-loop governance, meaning that AI will not act independently but will assist and not override ethical decision-making. Likewise, NHS Blood and Transplant (NHSBT) in the United Kingdom has incorporated AI in its logistics and allocation optimization and is regulated by the NHSX AI Ethics Framework. According to this framework, all AI tools must follow transparency, accountability, and explainability requirements and can be publicly reported and reviewed by clinicians (UK Department of Health, 2021). Another factor that strengthens the democratic legitimacy of the use of AI in NHSBT is the presence of independent patient and ethics boards.

Canadian Institutes of Health Research (CIHR) have published AI ethics principles with Indigenous and underrepresented communities to ensure that no bias and exclusion is recreated by clinical AI systems (CIHR, 2021). KSA, which has its own heterogeneous population, can follow the same participatory methods of governance.

A intriguing comparison is made with China where AI in organ setting and logistics has been scaled at a fast pace but with little transparency and consultation. It has been reported that the transplant outcomes are high, and there is regulatory obscurity and centralized leadership that is ethically questionable (Zhou and Pan, 2022). This

demonstrates how technocratic authoritarianism can be a danger to AI governance, which KSA should not follow due to its religious and other legitimacy demands.

These international precedents verify what the Regulatory Governance Theory stresses effective AI adoption in vital sectors does not only need innovation but the legitimacy of the law, providers accountability, and institutional control. Notably, it is important that legal, ethical, and technological controls are co-existent. In the case of KSA, it can be the creation of interconnected layers of governance, such as legal reforms, religious audits, AI-specific ethical review commissions, and sectoral coordination between SDAIA and SCOT, as well as the Ministry of Health.

Furthermore, such nations as the Netherlands and Germany are experimenting with algorithm registries, where all clinical AI tools will have to be registered and reviewed and made public (Sethupathy, 2021). This is in line with the epistemic transparency call - the inner logic of AI is readable, and arguably. This model can be applied to KSA creating an AI-ethics repository of transplantation systems where feedback on Shariah scholars, clinicians, and data scientists is sought.

The implementation of AI in organ transplantation presents more than technical problems, but there are multi-layered risks and normative dilemmas as well. Regulatory governance wise, these risks are legal, ethical, operational and religious.

To begin with, AI systems are data-driven in their nature. This brings about the issue of bias and representativeness. In case the transplant AI systems imported the training data of Western populations, this data might not be representative of the Saudi epidemiology reality and cause biased prioritization or allocation results (Gnanasambandan, & Balasubramanian, 2025). Algorithms decisions will jeopardize equity, going against international bioethics and Islamic *adl* unless enforced testing locally or contextually.

Second, AI in transplantation will result in non-transparency in decision-making, which is commonly known as the black box problem. Regulatory Governance Theory warns not to leave opaque systems to act without accountability regulation systems (Yeung, 2018). In such a setting as the one in

KSA, where there is a strong association of the legal accountability not only with the secular legal framework but also with the religious one, the lack of clarification of AI decisions can lead to ethical scandals, healthcare conflicts, or even lawsuits. To deal with this, the regulatory policies should formalize explainability as a condition that cannot be compromised.

Third, it has a liability dilemma. In case an AI-based system improperly suggests an organ recipient that will be hurt or die, who is responsible? Is it the software developer himself, the physician or even the regulatory body that approved the system? The existing Saudi law does not regulate the multi-actor liability of AI-mediated decisions. Tiered responsibility is suggested in comparative models like the EU AI Act, in which everyone in the AI pipeline has proportional responsibility (European Commission, 2021).

Fourth, it is still unclear how the problem of *Shariah* conformity is addressed in the algorithmic logic. It is possible that the AI systems encode the value judgments, unlike pharmaceuticals or medical devices, which do it implicitly. As an illustration, by giving priority to younger patients over older patients, depending on some statistical survival rates, a model will end up contravening unknowingly Islamic ethical principles within the context of dignity and elder care. Regulatory authorities should collaborate with Islamic jurists in scrutinizing AI models of the hierarchies of values embedded within them- setting *Shariah*-compliance certifications on AI systems.

Fifth, AI risks undermining the trust and legitimacy of the population in case it is seen to deprive the transplant of the human compassion or sensitivity to religion. Regulatory Governance Theory focuses on the fact that procedural fairness and involvement of stakeholders are imperative in validating the new instruments of governance. To make the implementation of AI more participatory rather than technocratic, KSA should investigate establishing citizen oversight councils, consisting of patients, ethicists, and *imams* (Islamic clerics).

Finally, at the operational level, there are inter-agency challenges like SDAIA, MOH, SCOT, and others, which create a hindrance to integrated governance. The fragmentation of regulations can

lead to overlapping mandates, lack of accountability and inconsistent standards- which according to Regulatory Governance Theory is a risky situation. This can be reduced by the implementation of a single AI-in-Health Regulatory Council, which would be an intersectoral standard-setting, review, and adaptation platform.

Conclusion

This paper has delved into the implementation of the concept of artificial intelligence (AI) in the organ transplantation sector in KSA with the view that strict legal and regulatory measures are necessary to regulate its application. Applying the Regulatory Governance Theory as the conceptual framework, the study has found out the significant gaps in the current legal framework of KSA, as it lacks AI-specific laws, ethical principles, and institutional resources to address the challenges of the algorithmic decision-making in the healthcare sector.

The results point to the fact that KSA is progressing enormously in its adoption of AI and healthcare digitalization, but the current regulatory framework is disjointed and not well-suited to regulate AI when it comes to high-stakes areas of organ transplantation. It is evident that the laws in time specific to the sector should be created that clarify the role of AI in decision-making, maintain the Shariah compliance and provide the mechanisms of the transparency and governance of the algorithms and data. Additionally, the research also shows that the Vision 2030 framework of the Kingdom, despite its potential, still lacks a more significant correlation between the technological goals and the legal framework that the ethical and legal use of AI demands.

Comparative best practices in other countries like the United States, the United Kingdom, and the European Union would be of great lessons in contrast. Those nations have managed to implement AI into organ transplantation and health care through the adoption of a set of ethical principles, legal regulations and control systems. The models used in KSA can highly be beneficial compared to the models that are adopted in the country, as these must be adapted to the Islamic bioethics and values of the people.

This paper underlines that AI is neither a technological tool nor merely a governance instrument that can define the future of healthcare in KSA. KSA will be able to balance technological innovativeness and societal responsibility, as well as ethical and religious responsiveness which will define the legal and regulatory preparedness to adopt AI in organ transplantation. The given gaps will be addressed through the multi-stakeholder cooperation of regulatory authorities, Islamic scholars, medical professionals, and data scientists to make sure that the use of AI can provide the public good without violating the ethical principles of Saudi society.

Although artificial intelligence has a huge potential to improve the efficiency and equality of organ transplantation, its effective implementation in the healthcare system of KSA needs a comprehensive regulatory framework. This framework will have the legal, ethical, technological and cultural components to build trust and guarantee that people have faith in AI-based healthcare systems. The research suggests the creation of AI-specific legislation, AI audit, Shariah-compliant regulation, and a framework of AI ethics, which will help KSA take a step in the direction of the future in which technology and humanity will live together in the healthcare system.

Recommendations

Based on the results and discussion of this paper, the subsequent recommendations can be made in the context of the legal and regulatory readiness of KSA to introduce the artificial intelligence (AI) into the organ transplantation framework. Such proposals are meant to bring the technological innovation to the same direction with ethical governance, legal clarity and institutional coordination.

- KSA ought to advance AI-related laws that are specific to the field of healthcare, and specifically organ transplantation. These legislations ought to explicitly specify the roles, responsibilities and liabilities of all the stakeholders who participate in the development and deployment of AI systems. The accountability of the algorithms, the informed consent of the AI-based decisions, and the right to explanation should also be presented in legal provision to patients who have been influenced by the automatic processes.

▪ The Saudi Center of Organ Transplantation (SCOT) should establish an independent AI and Organ Transplantation Oversight Committee that will include AI experts, clinicians, legal scholars, ethicists, and Islamic jurists. It should be the body that reviews, approves, and audits all AI tools in organ matching and allocation and makes sure that the tools adhere to national ethical standards and Islamic principles.

▪ Transplantation All AI systems used in transplantation should be highly transparent and auditable. This involves such things as public documentation of algorithms, regular third-party audits, and mechanisms to explain themselves. These conditions will guarantee the public responsibility and promote the trust of AI-supported decision-making.

▪ Based on the examples of the EU and the UK, KSA should establish a National Registry of Clinical AI Systems, in which all accepted AI algorithms in healthcare will be listed. The data in this registry should contain the information on the system performance, its intended use, ethical adherence, and feedback provided by clinicians and patients. This enhances epistemic openness and regulative and social examination.

▪ Better coordination of key stakeholders such as SDAIA, SCOT, the Ministry of Health, and Saudi Health Council are required. It should be emphasized that to make sure that AI implementation in healthcare is in line with national AI strategy, health policy goals, and legal protections, the multi-agency task force should be created.

▪ Considering the importance of Islamic values in Saudi governance, any AI system that impacts organ donation must go through Shariah ethics. The cooperation with such organizations as the Senior Scholars Council must be formalized to create Islamic AI ethics principles, keeping the AI decision-making in compliance with such principles like *maslahah* and *adl*.

▪ To prevent cultural and medical incompatibility, any artificial intelligence model designed outside of the Kingdom will have to be tested locally and contextually adjusted. This involves local clinical trials using local datasets to make sure the trials are relevant, less biased, as well as to adhere to local ethical and regulatory requirements.

▪ The ethical use of AI, the interpretation of algorithm results, and system failure are the areas that should be trained to clinicians and administrators. Medical education curricula throughout the nation must also integrate AI literacy to train future healthcare professionals to operate in decision environments that have been integrated with technology.

▪ To build trust in the population, the Saudi authorities should begin with awareness campaigns that would enlighten on the application of AI in organ donation and the protection of ethics. The AI might be introduced through mechanisms of public participation (citizen advisory boards) to make it look like an addition to fairness rather than a reduction of it.

▪ KSA should also conform to global standards, including the WHO AI Ethics Guidance, the EU AI Act, and the UNESCO AI Ethics Recommendations, as well as form regional alliances with other nations, such as the UAE and Qatar. Such partnerships will facilitate knowledge exchange and hasten the process of developing powerful governance models.

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