

TOWARDS ETHICAL AND LEGAL GOVERNANCE: INTEGRATING AI DIAGNOSTIC TOOLS FOR SIDS

Navneel Sharma, Neil Sharma** and Nashika Sharma****

The incorporation of artificial intelligence (AI) into medical diagnostic tools has the potential to significantly improve healthcare outcomes in Small Island Developing States (SIDS). However, it is critical to carefully consider the legal implications and risks associated with the implementation of those technologies. AI has the ability to greatly enhance healthcare in SIDS, but responsible implementation is critical. In emphasising the importance of understanding the distinct context of SIDS for effective implementation, this paper provides guidance to stakeholders. It aims to enhance decision-making processes, strategies, and optimise the utilisation of AI in healthcare settings, in order to contribute to improved services and health outcomes in these countries.

Le recours à l'usage de l'intelligence artificielle (IA) dans le domaine de la santé à commencer par l'établissement d'un diagnostic fiable, est source d'espoirs et un indéniable facteur de progrès dans les petits États insulaires en développement (PEID). Si l'IA a la capacité d'améliorer considérablement les soins de santé dans les PEID, cela doit se faire sous la réserve toutefois d'être mise en œuvre de manière responsable. Ainsi, il est fondamental de prendre en compte les implications juridiques et les risques associés à la mise en œuvre de ces nouvelles technologies. Les auteurs soulignent l'importance de la nécessité d'une appréhension et d'une maîtrise préalables des contextes sociaux et économiques distincts propres à chacun de ces États et territoires. Dans ce contexte, ils proposent

* Navneel Sharma is a legal academic with the University of the South Pacific and is currently a Doctoral candidate with the University. He was a former Director at the Ministry of Foreign Affairs in Fiji.

** Neil Sharma is a specialist Obstetrician and Gynaecologist; former Minister of Health and Medical Services for Fiji and Vice Chair of the 67th session of the World Health Assembly.

*** Nashika Sharma is a Senior Public Health Officer with the Fiji Ministry of Health and Medical Services who has previously worked as a public health consultant for the World Health Organization based in Suva, Fiji.

quelques pistes de réflexions dans les processus de prise de décision, les stratégies et l'optimisation de l'utilisation de l'IA dans les établissements de santé des PEID.

I OVERVIEW OF MEDICAL AI DIAGNOSIS TOOLS

A study conducted by the Johns Hopkins University School of Medicine found that an error or delayed diagnosis accounts for one-third of malpractice instances resulting in death or serious disability. Misdiagnosis is a major source of significant medical errors, accounting for an estimated 40,000 to 80,000 deaths each year in United States' hospitals. In addition, nearly 12 million Americans face a diagnostic error in a primary care environment each year, with 33% of these cases leading to serious or permanent injury or death.

The study, financed by the Society to Improve Diagnosis in Medicine, looked at nearly 55,000 malpractice cases from the Comparative Benchmarking System database. The study revealed that 74.1% of diagnostic errors that caused the most harm fell into three main groups, known as "The Big Three": cancer (37.8%), vascular events (22.8%), and infection (13.5%).

The top five diseases in each category accounted for 47.1% of all high-severity misdiagnosis related cases; and 63.5% of all high-severity cases within "The Big Three," respectively. Stroke was the most frequently misdiagnosed vascular disease; sepsis was the most frequently misdiagnosed infection; and lung cancer was the most frequently misdiagnosed cancer.¹

There is evidence indicating that medical AI diagnostic technologies can reduce human error. Several research investigations and tests have shown the capabilities of AI tools to boost diagnostic precision and efficacy, thus decreasing errors related to human variables.² AI diagnostic tools are computer-based systems that use advanced AI techniques to help healthcare professionals determine a wide range of medical diseases.³

1 John Hopkins Medicine "Report Highlights Public Health Impact of Serious Harms From Diagnostic Error in U.S." (2023) <<https://www.hopkinsmedicine.org/news/newsroom/news-releases/2023/07/report-highlights-public-health-impact-of-serious-harms-from-diagnostic-error-in-us>>.

2 Asan O, Bayrak AE, and Choudhury A "Artificial intelligence and human trust in healthcare: focus on clinicians" (2020) Journal of Medical Internet Research <<https://www.jmir.org/2020/6/e15154/>>.

3 Ahmad Z, Rahim S, Zubair M and Abdul-Ghafar J "Artificial intelligence (AI) in medicine, current applications and future role with special emphasis on its potential and promise in pathology: present and future ... Diagnostic pathology" (2021) <<https://link.springer.com/article/10.1186/s13000-021-01085-4>>.

These groundbreaking technologies have altered the healthcare industry by incorporating cutting-edge technology. It can provide potential diagnoses or make important recommendations by assessing a variety of patient data, including symptoms, medical history, and test results.⁴ It can sort through huge quantities of medical data by the use of advanced algorithms and machine learning capabilities. This enables it to identify intricate patterns and relationships that humans alone would find hard to detect. Such tools are significant resources for healthcare practitioners because of their outstanding ability to analyse complex data, and therefore to make more precise and effective diagnoses.⁵

It is indisputable that AI tools have the potential to revolutionise the healthcare business, ultimately leading to unprecedented improvements in patient outcomes and treatment quality.⁶

II CURRENT APPLICATIONS OF AI DIAGNOSIS TOOLS IN HEALTHCARE

Medical AI diagnosis is currently applied in a wide range of healthcare settings. For example, tools are used in radiology to detect anomalies in imaging tests that include X-rays and MRI scans. These methods also assist pathologists to review histopathology slides to locate malignant cells or aberrant tissues. Furthermore, they are used in clinical settings to analyse patient data and offer therapies, anticipate the onset of disease, and offer decision support.⁷ Other further notable applications are the following:

-
- 4 Fujita, H "AI-based computer-aided diagnosis (AI-CAD)" (2020) the latest review to read first. Radiological physics and technology <file:///C:/Users/Navneel/Downloads/Fujita-2020-Radiological_Physics_and_Technology.pdf>.
 - 5 Ahmed Z, Mohamed K, Zeeshan S, and Dong XQ "Artificial intelligence with multi-functional machine learning platform development for better healthcare and precision medicine" (2020) <<https://academic.oup.com/database/article/doi/10.1093/database/baaa010/5809229?login=false>>
 - 6 Above n 3.
 - 7 Rauschecker AM, Rudie JD, Xie L, Wang J, Duong MT, Botzolakis EJ, and Gee JC "Artificial intelligence system approaching neuroradiologist-level differential diagnosis accuracy at brain MRI" (2020) 295(3) Radiology 626-637 <<https://pubs.rsna.org/doi/pdf/10.1148/radiol.2020190283>>.

IBM Watson for Oncology is an innovative system which utilises medical literature, clinical trial data, and patient records to help oncologists to identify personalised and evidence-based treatment options for cancer patients;⁸

Google DeepMind's Streams is an AI-powered application created specifically for assisting healthcare professionals to efficiently prioritise patients based on the severity of their conditions. It has proved to be especially helpful in the treatment of kidney diseases;⁹

PathAI uses modern algorithms for machine learning to assist pathologists accurately identify diseases by analysing pathology slides. This innovative technology greatly enhances the efficiency and accuracy of pathology diagnostics;¹⁰

Zebra Medical Vision concentrates on the use of AI to analyse medical imaging data such as X-rays, CT scans, and MRIs. Its main purpose is to aid in the early detection of an array of diseases, including cardiovascular and liver conditions;¹¹

Tempus utilises AI to thoroughly analyse clinical and molecular data, permitting oncologists to make more informed decisions concerning cancer treatment. The platform aims at generating tailored therapies according to a patient's distinctive genetic profile;¹²

AIDoc Medical uses algorithms based on deep learning to analyse medical images and identify anomalies such as fractures or abnormalities in CT scans and X-rays;¹³

-
- 8 Chua IS, Gaziel-Yablowitz M, Korach ZT, Kehl KL, Levitan NA, Arriaga YE, and Hassett M "Artificial intelligence in oncology: Path to implementation" (2021) 10(12) *Cancer Medicine* 4138-4149 <<https://onlinelibrary.wiley.com/doi/pdf/10.1002/cam4.3935>>.
 - 9 Chen M and Decary M "Artificial intelligence in healthcare: An essential guide for health leaders" (2020) *Healthcare management forum* <<https://journals.sagepub.com/doi/full/10.1177/0840470419873123>>.
 - 10 Baxi V, Edwards R, Montalto M, and Saha S "Digital pathology and artificial intelligence in translational medicine and clinical practice" (2022) <<https://www.sciencedirect.com/science/article/pii/S0893395222003477>>.
 - 11 Alexander A, Jiang A, Ferreira C, and Zurkiya D, "An intelligent future for medical imaging: a market outlook on artificial intelligence for medical imaging" (2020) 17(1) *Journal of the American College of Radiology* 165-170 <<https://www.sciencedirect.com/science/article/pii/S1546144019308634>>.
 - 12 Tsimberidou AM, Kahle M, Vo HH, Baysal MA, Johnson A, and Meric-Bernstam F "Molecular tumour boards—current and future considerations for precision oncology" (2023) 20(12) *Nature Reviews Clinical Oncology* 843-863 <<https://www.nature.com/articles/s41571-023-00824-4>>.
 - 13 Roy S, Meena T, and Lim SJ, "Demystifying supervised learning in healthcare 4.0: A new reality of transforming diagnostic medicine" (2022) <<https://www.mdpi.com/2075-4418/12/10/2549>>.

The Butterfly iQ+ uses AI to aid healthcare professionals obtain and interpret ultrasound images. The device was created to enhance accessibility and ease of use in ultrasound diagnostics;¹⁴

IDx-DR is an FDA-approved AI system that is specifically designed to detect diabetic retinopathy. This advanced system recognises signs of the condition by analysing retinal images, enabling early treatment to prevent vision loss;¹⁵

Prognos effectively uses AI to detect and predict disease risks via clinical laboratory data. Its primary focus is on applying data to improve patient outcomes while lowering healthcare costs.¹⁶

Ada Health is an advanced AI-powered symptom checker and health assistant. Employing a vast amount of medical knowledge, the platform helps users to understand their symptoms while offering information on potential conditions, thereby encouraging health literacy and well-informed decision-making.¹⁷

III HEALTH CARE ISSUES IN SMALL ISLAND DEVELOPING STATES

SIDS face a number of challenges that delay or limit the seamless use and optimal operation of AI diagnosis tools. The motivation for research is based on the growing use and integration of sophisticated and complex AI in breakthrough medical diagnostic systems. This demonstrates not just its growing importance, but also the unique and complex issues that SIDS face within the huge global healthcare arena.¹⁸

SIDS are frequently distinguished by their small land areas, fragile ecosystems, and limited resources. Because of their geographical isolation and vulnerability to

14 Malik AN, Rowland J, Haber BD, Thom S, Jackson B, Volk B, and Ehrman RR "The use of handheld ultrasound devices in emergency medicine" (2021) 9(3) *Current Emergency and Hospital Medicine Reports* 73-81 <<https://link.springer.com/article/10.1007/s40138-021-00229-6>>.

15 Sedova A, Hajdu D, Datlinger F, Steiner I, Neschi M, Aschauer J, and Pollreisz A "Comparison of early diabetic retinopathy staging in asymptomatic patients between autonomous AI-based screening and human-graded ultra-widefield colour fundus images" (2022) 36(3) *Eye* 510-516. <<https://www.nature.com/articles/s41433-021-01912-4>>.

16 Above n 5.

17 Above n 9.

18 Nel R, Mearns KF, Jordaan M, and Goethals P "Towards understanding the role of islandness in shaping socio-ecological systems on SIDS: The socio-ecological islandness concept" (2021) *Ecological Informatics* <<https://www.sciencedirect.com/science/article/abs/pii/S1574954121000558>>.

external shocks, SIDS confront considerable hurdles in providing critical services such as healthcare.¹⁹

The lack of infrastructure is a pressing issue for SIDS. Many provide medical facilities like hospitals, clinics, and specialist institutions. As a result, the public has limited access to essential medical services. People often have to travel long distances or even leave their island to get the care they require. This lack of healthcare infrastructure not only delays and hinders treatment, but it also increases the system's already heavy loads. This naturally leads to increased gaps in healthcare and poorer health outcomes for the SIDS' population. In addition, the lack of adequate healthcare facilities reduces the number of healthcare workers in these places, making recruiting and retention difficult. Addressing the immediate issue of inadequate healthcare facilities is critical to improving the general health and well-being of SIDS populations. Significant investment is required to construct and develop healthcare facilities.²⁰

SIDS are also experiencing a scarcity of medical workers, which has an important impact on the healthcare systems. The scarcity of doctors, nurses, and other healthcare professionals in SIDS makes it difficult to offer effective and comprehensive care to the people. The lack of medical staff is sometimes linked to causes such as emigration, restricted training options, and the opportunities provided by larger countries.²¹ A prominent health practitioner in Fiji has warned that the migration of nurses from Fiji places severe pressure on the country's health care system. According to Dr Eddie McCaig, nurses are departing in large numbers with over 800, or more than a quarter of the workforce, going overseas in 2019 alone. Dr McCaig told participants at the inaugural National Economic Summit in Suva that healthcare workers were departing for an assortment of reasons, including poor pay and working conditions, a challenging political environment, and the desire to provide better opportunities for their children.²² As a result of the shortfall, there are increased wait times for medical consultations and treatments. Addressing this issue

19 Leal Filho W, Ha'apio, MO, Lütz JM, and Li C "Climate change adaptation as a development challenge to small Island states: A case study from the Solomon Islands. *Environmental Science & Policy*" (2020) <<https://e-space.mmu.ac.uk/625652/1/Deposit.ClimateChangeand%20Solomon%20Islands.pdf>>.

20 Ibid.

21 Foley AM, Moncada S, Mycoo M, Nunn P, Tandrayen-Ragoobur V, and Evans C "Small island developing states in a post-pandemic world: Challenges and opportunities for climate action" (2022) 13(3) *Wiley Interdisciplinary Reviews: Climate Change* e769. <<https://wires.online.library.wiley.com/doi/pdf/10.1002/wcc.769>>.

22 Radio New Zealand "Exodus of Health Workers in Fiji. *Radio New Zealand*" (2023) <<https://www.mz.co.nz/international/pacific-news/488395/exodus-of-of-health-workers-in-fiji>>.

through initiatives such as training programmes, incentives, and recruitment activities is essential for improving SIDS' healthcare personnel and enhancing overall healthcare delivery.

Furthermore, SIDS are currently struggling with a lack of access to essential medicines. Due to limited resources and financial limitations, people struggle to buy or obtain essential medications, resulting in inadequate treatment and substandard healthcare.²³

Finally, SIDS frequently face a high disease load, from communicable and noncommunicable diseases like malaria, dengue fever, diabetes, cardiovascular disease, tuberculosis, HIV/AIDS, cancer, respiratory ailments, and mental health issues.²⁴

Furthermore, SIDS have specific public health risks due to their physical position, such as vulnerability to natural catastrophes such as hurricanes, typhoons, earthquakes, volcanic eruptions, floods, and tsunamis. Climate change increases these challenges, increasing the likelihood of food and water insecurity, vector-borne diseases, coastal erosion, and population displacement.

IV AI DRIVEN SOLUTIONS TO SIDS HEALTH CARE ISSUES

In locations without adequate healthcare infrastructure, AI tools offer a significant breakthrough as they enable remote diagnosis of ailments. Patients may collect essential health data using inexpensive gadgets or cell phones due to AI-driven systems that prioritise simplicity and accessibility. This information is able to be transmitted and assessed from a distance, reducing the requirement for costly medical equipment and substantial physical infrastructure. Furthermore, cloud-based solutions simplify the creation of AI tools, offering broad diagnostic capabilities without the burden of local infrastructure.²⁵

AI has the capacity to address the lack of medical personnel by automating monotonous operations. AI-powered diagnostic systems can do preliminary tests and

23 Thomas A, Baptiste A, Martyr-Koller R, Pringle P, and Rhiney K "Climate change and small island developing states" (2020) 45 Annual Review of Environment and Resources 1-27. <<https://www.annualreviews.org/doi/full/10.1146/annurev-environ-012320-083355>>.

24 Sanders D "The struggle for health: medicine and the politics of underdevelopment" (2023) <https://scholar.google.com/citations?view_op=view_citation&hl=en&user=1pHQ5YwAAAAJ&citation_for_view=1pHQ5YwAAAAJ:buQ7SEKw-1sC>.

25 Schwalbe N, and Wahl B "Artificial intelligence and the future of global health" (2020) The Lancet <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7255280/>>.

basic diagnostics, and enable medical professionals to focus on more difficult cases. AI-powered decision support systems offer significant insights and recommendations, improving capacity of present medical workers.²⁶

AI plays an important role in improving prescription patterns through thorough data analysis. AI ensures that accessible pharmaceuticals are used effectively by identifying the most suitable prescription methods that are best suited to patient characteristics, medical history, and regional health trends. Furthermore, AI serves to optimise the supply chain, correctly estimate demand, mitigate shortages, and improve distribution efficiency. This comprehensive method helps to assure a consistent and easily accessible supply of critical pharmaceuticals.²⁷

AI's early detection and prevention capabilities make an important contribution to decreasing illness burden. AI systems examine large databases to detect illness trends in their early stages, allowing for timely intervention and treatment. Additionally, AI-enabled population health management utilises demographic and health data to identify high-risk groups, enabling targeted interventions that proactively manage and reduce disease prevalence.²⁸

V LEGAL FRAMEWORK FOR MEDICAL AI DIAGNOSIS TOOLS

Collaboration between the legal profession and medical breakthroughs is critical for developing a healthcare system that prioritises ethical practices, patient entitlements, and public welfare. Legal frameworks play an important role in providing ethical supervision, ensuring that medical advancements align with social norms. Legal restrictions help to protect patients' rights and confidentiality while also promoting transparency and informed consent. Healthcare practitioners are held accountable to high standards through legal processes, encouraging ongoing improvement in healthcare provision. In this symbiotic relationship, the law acts as

26 Lyon JY, Bogodistov Y, and Moormann J "AI-driven Optimization in Healthcare: the Diagnostic Process" (2021) 29(4) *European Journal of Management Issues* 218-231 <<https://mdu.dp.ua/index.php/MI/article/view/343>>.

27 Toorajipour R, Sohrabpour V, Nazarpour A, Oghazi P, and Fischl M "Artificial intelligence in supply chain management: A systematic literature review" (2021) 122 *Journal of Business Research* 502-517 <<https://www.sciencedirect.com/science/article/pii/S014829632030583X>>.

28 Kumar Y, Koul A, Singla R, and Ijaz MF "Artificial intelligence in disease diagnosis: a systematic literature review, synthesizing framework and future research agenda" (2023) 14(7) *Journal of ambient intelligence and humanized computing* 8459-8486. <<https://link.springer.com/article/10.1007/s12652-021-03612-z>>.

a guiding force, ensuring that medical advances are consistent with ethical standards, individual rights, and societal well-being.²⁹

It should be noted that a legal framework for medical AI diagnosis tools in SIDS is critical for controlling their use and ensuring patient safety. This framework encompasses both national laws and regulations, international agreements and norms, and ethics. These legal elements form the foundation for overseeing the development, implementation, and operation of medical AI diagnosis technologies. Such rules address an array of challenges through the establishment of norms and standards, including licensing, certification, quality control, and patient consent. They also outline the duties and responsibilities of healthcare professionals, manufacturers, and organisations involved in the creation and use of these instruments. Compliance with these rules is critical for minimising potential dangers and ensuring ethical behaviour.

VI INTERNATIONAL AGREEMENTS AND GUIDELINES

International agreements and recommendations offer direction and standards for the use of AI diagnosis tools in SIDS. Organisations like the World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF) collaborate in order to create and support worldwide rules, agreements, and standards.³⁰ These instruments aim to harmonise regulations, promote interoperability, and address ethical considerations on a global scale.

International cooperation is essential for SIDS to gain access to important resources, expertise, and best practices for improving their legal systems. These agreements and standards serve as essential reference points for governments, regulatory agencies, and healthcare practitioners to ensure the safe, efficient, and responsible use of AI tools. Ultimately, this benefits patients and the entire healthcare ecosystem in SIDS. These international agreements provide a strong framework for the application of AI in healthcare, which will enhance results, boost productivity, and advance medical research. SIDS have the potential to utilise these frameworks in order to surmount budget constraints, improve public health campaigns, and hasten the attainment of universal healthcare coverage. Through these agreements and recommendations, SIDS can construct robust regulatory

29 Van Kolschooten H "EU regulation of artificial intelligence: challenges for patients' rights"(2022) *Common Market Law Review*. <https://www.researchgate.net/publication/360300367_EU_regulation_of_artificial_intelligence_Challenges_for_patients%27_rights>.

30 Miao F, Holmes W, Huang R, and Zhang H "AI and education: A guidance for policymakers" (2021) <<https://discovery.ucl.ac.uk/id/eprint/10130180/>>.

frameworks, efficient quality assurance procedures, and promote stakeholder participation with support and expertise.

This cooperative strategy encourages the exchange of best practices and knowledge between countries while permitting the morally and responsibly applied use of AI tools. This makes it feasible for SIDS to use AI's transformative potential to reform healthcare systems, encourage fresh approaches to medicine, and improve patient outcomes.

VII NATIONAL LAWS AND REGULATIONS

There are various national laws and regulations that allow, restrict, and oversee the use of AI diagnostic tools. For example, the General Data Protection Regulation (GDPR) is a European Union mandate which stresses informed consent and openness in AI-driven diagnosis. This regulation requires compliance and protects patient information. The European Union's Medical Device Regulation also specifies safety and performance criteria for AI-based diagnostic tools, ensuring that they meet the specified standards.³¹

Similarly, in the United States, the Health Insurance Portability and Accountability Act sets high criteria for patient data protection, necessitating that AI technologies conform with these rules. In the United States as well as Japan, regulations such as the Digital Health Technology Vision and the Medical Device Act aim to ensure that AI is used effectively, safely, and ethically in healthcare.³²

Singapore's Digital Health Technology Vision creates a framework for evaluating and regulating digital health technologies, including AI in healthcare, while China's Personal Information Protection Law and Australia's Therapeutic Goods Administration prioritise data protection and regulatory scrutiny for AI diagnostic tools.³³

These examples emphasise the global commitment to creating national regulations that safeguard patient safety, privacy, and ethical standards in the fast-evolving field of medical AI diagnosis tools.

Nations in the Caribbean region that are members of the Caribbean Community and Common Market (CARICOM) may not have national laws in place for medical AI diagnosis tools. However, coordinated efforts within CARICOM can influence

31 Gerke S, Minssen T, and Cohen G "Ethical and legal challenges of artificial intelligence-driven healthcare" (2020) *Artificial intelligence in healthcare* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332220/>>.

32 *Ibid.*

33 *Above at n 31.*

the development of regional standards and norms. These community-wide activities may result in a more coordinated approach to the ethical use of AI in healthcare. Similarly, Pacific states, as the Pacific Island Forum (PIF) members, are more inclined to work together to address shared concerns. This explicit legislation on medical AI may not be widely adopted, regional cooperation within the PIF could spur the establishment of shared norms or standards. The Pacific region's joint efforts may have an impact on ethical AI technology adoption.

VIII ETHICAL CONSIDERATIONS

In the field of healthcare, the collaboration between law and medical ethics is essential in developing a robust and dependable system. The two professions have an inextricable connection with the safety and well-being of patients. Legal norms and ethical principles work together to emphasise the best interests of persons while upholding high moral standards. It is worth highlighting that, while regulations serve as required bounds, ethics extends beyond mere compliance to the promotion of patient autonomy, privacy, and fair treatment.³⁴

Ethical considerations are essential in the setting of medical AI diagnosis tools in SIDS. As these tools rely on algorithms and machine-learning approaches, transparency and accountability are essential ethical standards. The design, development, and implementation of AI diagnosis systems must stress fairness, accuracy, and bias avoidance. In addition, ethical principles cover topics like as patient autonomy, informed consent, and healthcare professionals' responsibility to ensure human monitoring and intervention.³⁵ The combination of law and medical ethics goes beyond mere compliance and encompasses a comprehensive approach.³⁶

Ethics frameworks for AI in healthcare also deal with the duty of manufacturers and organisations to do extensive testing, maintain data privacy and security, and upgrade the tools' usefulness and safety. By adhering to ethical guidelines, SIDS can

34 Doherty RF "Ethical dimensions in the health professions-e-book" (2020) <https://books.google.com.fj/books?hl=en&lr=&id=N1cBEAAAQBAJ&oi=fnd&pg=PP1&dq=L+egal+standards+and+ethical+principles+work+together+to+prioritize+patient+safety+and+well-being.&ots=blzxapKF7x&sig=jDuuk3Q_nUPeF2x69MsOcZcE4kk&redir_esc=y#v=onepage&q&f=false>.

35 Madaio M, Egede L, Subramonyam H, Wortman Vaughan J, and Wallach H "Assessing the Fairness of AI Systems: AI Practitioners' Processes, Challenges, and Needs for Support. Proceedings of the ACM on Human-Computer Interaction" (2022) 6(CSCW1), 1-26. <<https://arxiv.org/pdf/2112.05675.pdf>>.

36 Varkey B "Principles of clinical ethics and their application to practice" (2021) Medical Principles and Practice <<https://karger.com/mpp/article-pdf/30/1/17/3128579/000509119.pdf>>.

create trust in the use of medical AI diagnosis tools and enable equitable access to quality healthcare services.

IX LIABILITY RISKS AND CHALLENGES

Medical liability risks and its challenges shape standards of care, guide informed consent, and control malpractice proceedings. They play a significant part in establishing accountability, patient safety, and compensation mechanisms within the healthcare system, since they create the basis for healthcare professionals' obligations, patient rights, and dispute resolution.

In the context of utilising AI diagnosis tools in SIDSs, it is imperative to thoroughly evaluate the potential liability risks and challenges associated with their use. Should these tools be inadequately designed, implemented, or monitored, there is a considerable risk of causing harm to patients. It is critical that governments and healthcare professionals address these liability risks and problems in order to ensure patients' well-being and safety.³⁷

A Potential Harm to Patients

The possible use of AI medical diagnosis technologies in SIDS raises serious issues. This is owing to the unique obstacles that these locations experience. Any inconsistencies or errors in these tools could lead to misdiagnoses, thereby aggravating health conditions due to the scarcity of medical care.³⁸ Trust in the healthcare system is critical, and any harm produced by AI technologies has the potential to erode this trust. Furthermore, SIDS may lack the infrastructure required to quickly address the implications of AI-related medical blunders. In resource-constrained environments, misdiagnoses could have long-lasting effects, straining already limited healthcare facilities. The economic consequences are also significant, as SIDS may struggle to compensate individuals for any suffering caused by AI.

37 Health Organization, W.o.r.l.d. "Ethics and governance of artificial intelligence for health: WHO guidance" (2021) <https://books.google.com/fj/books?hl=en&lr=&id=csZqEAAAQBAJ&oi=fnd&pg=PR7&dq=Patient+responsibility+is+crucial+for+preventing+diseases+and+promoting+health+in+communities.&ots=xKQ0b4llvw&sig=p36OEoLk5VVKQRA1S0oIzXRio&redir_esc=y#v=onepage&q=Patient%20responsibility%20is%20crucial%20for%20preventing%20diseases%20and%20promoting%20health%20in%20communities.&f=false>.

38 Xue P, Ng MTA, and Qiao Y "The challenges of colposcopy for cervical cancer screening in LMICs and solutions by artificial intelligence" (2020) BMC medicine. <<https://link.springer.com/article/10.1186/s12916-020-01613-x>>.

B Accountability and Responsibility

Patient accountability and responsibility are critical components of the SIDS healthcare scene. Given the specific obstacles that SIDS presents, individuals are frequently encouraged to take an active role in controlling their own health. Patient responsibility is critical for optimal resource utilisation and the sustainability of healthcare systems, given the limited healthcare resources. Furthermore, SIDS's geographical isolation emphasises the value of patients taking responsibility for providing timely access to healthcare services and promoting their personal well-being. The vulnerability of SIDS to natural disasters stresses the importance of patient accountability in disaster preparedness. Individuals can contribute to their own and their communities' resilience during natural disasters by keeping personal health records, following treatment regimens, and implementing preventive health actions. When it comes to preventable diseases, patient responsibility becomes essential to disease prevention and health promotion.³⁹

Individuals can lessen the load on limited healthcare infrastructure by living a healthy lifestyle, participating in preventative measures, and receiving immunisations on time. SIDS' cultural dynamics and close-knit communities are consistent with the concept of patient accountability, which stresses community responsibility for health. Furthermore, given the budgetary limits confronting these countries, patient responsibility becomes even more critical in managing chronic illnesses and providing cost-effective treatment.⁴⁰

Aside from self-care programmes and patient's personal initiatives, it can be difficult to define who should be held accountable for the outcomes of AI diagnostic tools. Medical AI Diagnosis Tools use complicated algorithms and machine-learning approaches to assess medical data and provide diagnoses. AI can misdiagnose patients leading to potentially harmful therapies.⁴¹ The lack of adequate validation and regulatory supervision heightens the dilemma, as patients may receive erroneous

39 Above n 37.

40 Walker IF, Asher L, Pari A, Attride-Stirling J, Oyinloye AO, Simmons C, and Gibson RC "Mental health systems in six Caribbean small island developing states: a comparative situational analysis" (2022) 16(1) *International Journal of Mental Health Systems* 1-16 <<https://ijmhs.biomedcentral.com/articles/10.1186/s13033-022-00552-9>>.

41 Data entry can also be an issue.

information regarding their medical condition. There are various parties engaged, such as healthcare providers, software developers, and regulatory organisations.⁴²

C Professional Liability

Doctors Thomas Dratsch and Xue Chen, along with colleagues from Germany and The Netherlands, carried out an experiment involving radiologists. They were entrusted with analysing mammograms and awarding a score based on the well-known BI-RADS scoring system to indicate the degree of suspicion for breast cancer. The BI-RADS grading system runs from 1 to 6, with 1 representing normal and 6 indicating biopsy-proven malignancy.

There were both novice and experienced radiologists among the participants. In addition, radiologists were informed that they would be working with a new AI system that would calculate a BI-RADS score for each case on its own.

Radiologists could resort to this AI score when establishing their own diagnosis. However, unbeknownst to the human radiologists, the alleged AI system was actually a convincing counterfeit. In some situations, the AI system delivered an accurate score based on the actual mammography, however in others, the AI-generated score was purposefully manipulated to be higher or lower than the truth. All mammograms utilised in the study were obtained between 2017 and 2019. This enabled the researchers to access the real-world clinical outcomes for the patients in the past four years.

The findings included data on individuals who truly benign mammograms and those who were diagnosed with breast cancer by biopsy. Drs Dratsch and Chen discovered that when radiologists were given accurate AI-generated scores, their human interpretations of the mammograms were fairly accurate and consistent with the AI scores. However, when the AI-generated scores were deliberately incorrect, the radiologists' accuracy dropped to less than 20%. Even radiologists who had more than 10 years of experience, exhibited a significant decline in accuracy from 82% to 45.5% when they were given an incorrect AI score.⁴³

Accountability can be understood as the wider notion of being held responsible for one's actions. Responsibility, on the other hand, refers to the fulfilment of duties and obligations. Professional liability, which focuses on legal repercussions for

42 Habli I, Lawton T, and Porter Z "Artificial intelligence in health care: accountability and safety" (2020) 98(4) Bulletin of the World Health Organization 251 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7133468/>>.

43 Gaube S, Suresh H, Raue M, Merritt A, Berkowitz SJ, Lerner E, and Ghassemi M "Do as AI say: susceptibility in deployment of clinical decision-aids" (2021) 4(1) NPJ digital medicine 31 <<https://www.nature.com/articles/s41746-021-00385-9>>.

professional misconduct or negligence, is a legal facet of responsibility. Although both accountability and responsibility may involve ethical and professional considerations, professional liability specifically addresses the legal implications and consequences within a professional setting.⁴⁴

D Data Privacy and Security

Prioritising patient data protection and confidentiality is critical for SIDS. These specific settings meet unusual obstacles due to their inadequate healthcare infrastructure and increased sensitivity to cybersecurity concerns.⁴⁵ Given the interdependence of SIDS healthcare systems, any data security incident can have grave repercussions, including service outages and compromised patient care.

Given SIDS' sensitivity to global health hazards, the need of data security in responding to health emergencies cannot be over emphasised. Economic and societal consequences, such as loss of trust and potential effects on tourism, highlight the importance of prioritising patient data protection. To protect sensitive health information, it is necessary to strengthen regulatory frameworks and provide a legal foundation.

X MITIGATION STRATEGIES AND RECOMMENDATIONS

Establishing clear lines of accountability is critical to ensuring that the appropriate persons are held accountable in the event of a misdiagnosis or patient harm. This can be accomplished by developing frameworks and guidelines outlining the roles and duties of each stakeholder involved in the development, deployment, and operation of these technologies.⁴⁶

To ensure the well-being and safety of patients in SIDS, healthcare practitioners and policy makers must carefully examine and control any possible harm associated with these instruments. This can be accomplished by adopting comprehensive

44 Naik N, Hameed BM, Shetty DK, Swain D, Shah M, Paul R, and Somani BK "Legal and ethical consideration in artificial intelligence in healthcare: who takes responsibility?" (2022) 9 *Frontiers in surgery* 266 <https://www.frontiersin.org/articles/10.3389/fsurg.2022.862322/full?gclid=Cj0KCQiAjbagBhD3ARIsANRrqsSbECBHyiNltKKBRXm4CkJOwBot_U3M1rDu9zP0GaORA5bEfrypoaAtqFEALw_wcB>.

45 Connell J, Lowitt K, Saint Ville A, and Hickey GM "Food security and sovereignty in Small Island developing states: Contemporary crises and challenges" (2020) *Food security in small island states* 1-23. <https://link.springer.com/chapter/10.1007/978-981-13-8256-7_1>.

46 Esmailzadeh P, Mirzaei T, and Dharanikota S "Patients' perceptions toward human-artificial intelligence interaction in health care: experimental study" (2021) 23(11) *Journal of medical Internet research* e25856 <<https://www.jmir.org/2021/11/e25856/>>.

validation processes and regulatory frameworks, as well as ensuring that healthcare providers have the requisite knowledge and abilities to understand and apply the outputs of such tools.⁴⁷

It is crucial for healthcare professionals to understand the limitations of these tools and exercise their professional judgement when interpreting and acting on their output. Clear guidelines and training programmes should be developed to educate healthcare professionals on the appropriate use and integration of these tools into clinical practice. Establishing a framework for professional liability and accountability is essential to ensure the highest standard of care and protect healthcare professionals from unwarranted legal risks.⁴⁸

Collaboration among healthcare professionals, governments, AI developers, and stakeholders is necessary. Establishing interdisciplinary working groups and information-sharing platforms can help to facilitate the exchange of best practices, research discoveries, and problems associated with AI in medical diagnostics. This collaborative approach not only improves the understanding of legal frameworks and encourages the widespread use of AI tools.

XI CONCLUSION

The incorporation of AI into medical diagnosis tools represents a possible route for considerably improving SIDS' healthcare results. This paper emphasises the significance of having a thorough awareness of the legal framework and liability issues related with the use of AI diagnosis techniques in SIDS. This study acts as a guide for stakeholders by shedding light on critical legal liability concerns and giving significant insights to inform decision-making processes.

The findings presented here highlight the importance of ethical AI technology implementation in healthcare for SIDS. While artificial intelligence has the potential to transform medical diagnoses and improve services, the importance of carefully considering legal issues in order to limit potential risks must be emphasised. Sharing the study's findings with stakeholders allows for the development of effective strategies, ensuring the responsible and optimal use of AI in healthcare settings.

Finally, the discussion and considerations in this paper will contribute to the continuing discussion of the use of AI diagnosis in SIDS. A balanced strategy is

47 Wang C, Liu S, Yang H, Guo J, Wu Y, and Liu J "Ethical considerations of using ChatGPT in health care" (2023) 25 Journal of Medical Internet Research e48009 <<https://www.jmir.org/2023/1/e48009/>>.

48 Neri E, Coppola F, Miele V, Bibbolino C, and Grassi R "Artificial intelligence: Who is responsible for the diagnosis?" (2020) La radiologia medica <<https://link.springer.com/article/10.1007/s11547-020-01135-9>>.

advocated that capitalises on technological benefits while addressing legal concerns. By encouraging responsible deployment and informed decision-making, stakeholders may work together to improve healthcare services and outcomes in SIDS through the prudent use of AI.

