Health Technology Assessment of Artificial Intelligence in Radiology Within Kenya; Multicriteria Decision Analysis

Miriam Miima

Admin No: 165752

Master of Business Administration in Health Care Management

2025

Health Technology Assessment of Artificial Intelligence in Radiology Within Kenya; Multicriteria Decision Analysis

Miriam Miima
Admin No: 165752

Dissertation Submitted in Partial Fulfillment of The Requirements for The Degree of Master of Business Administration- Health Care Management at Strathmore University

March, 2025

DECLARATION

I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

The thesis of Miriam Miima was reviewed and approved for examination by the following

Name of Candidate: Miriam Miima Signature: Date: 12th March, 25

Approval

Supervisor:
Dr John Olukuru Signature: Date: 12th March, 25
Strathmore University Business School.

Dr. Ceaser Mwangi
Executive Dean, Strathmore University Business School.

Dr. Bernard Shibwabo
Director Office of Graduate Studies, Strathmore Business School.

ABSTRACT

Enhanced technology in healthcare improves patient outcomes, stream lines operations and enhances diagnostic capacity. Enhanced diagnostic capacity is fueled by advanced development and adoption of artificial intelligence (AI) solutions. Europe and North America have made bigger strides in the regulation and implementation of AI in radiology compared to Africa and Asia. AI technology can be developed locally or imported for implementation. Assessment of software as a medical device locally remains unclear which affects comprehensive standardization and articulation of its value proposition. This informs the need for a health technology assessment (HTA) tool for systemic appraisal of economic, social, ethical and clinical health care priorities in Kenya. Radiologists in America and Europe demonstrate that embedding user centered artificial intelligence in radiology improves efficiency and effectiveness in the radiology workflow. Few radiologists use AI in radiology within Kenya and more are willing to train artificial intelligence models despite multi factorial barriers. A normative assessment framework remains unclear in the design, development and clinical implementation of AI in radiology within Kenya. This study developed a health technology assessment (HTA) tool for AI in radiology using a hypothetical AI lesion detection software for pulmonary embolism (PE) on computed tomography pulmonary embolism (CTPA) images. The study evaluated AI in radiology using radiology multi-society practical considerations (MSC), the radiology AI deployment and assessment rubric (RADAR), and developed a local HTA tool for AI in radiology. Relevant institutional ethical permission was granted, data privacy and confidentiality was observed. The tool was piloted among 3 domain experts for construct and face validity, data was collected from 54 decision makers through online surveys and extracted into spreadsheets for analysis. This was an action research methodology on deductive themes analyzed using a multicriteria decision analysis (MCDA). Descriptive proportions were presented using categorical data where majority of the participants favored the third iteration of the tool. Inferential statistics analyzed using SPSSv25 confirmed intra class correlation co efficient using Cronbach $\alpha>0.7$ with significant reliability ($p=0.001$) for each deductive theme. Each item on the final HTA tool demonstrated statistical significance ($p>0.05$). Despite hypothetical application of the AI software, HTA tool provides a foundation for comprehensive evaluation of AI in radiology with good reliability. The HTA tool iteratively supports multicriteria decision making among strategic decision makers on AI in radiology against global standards.

Key words: *Health technology assessment, Artificial Intelligence, Radiology, Multicriteria Decision Analysis*

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACKNOWLEDGEMENTS

I wish to acknowledge with the warmest gratitude my supervisor Dr. John Olukuru. I am indebted to his guidance, patience and support in fostering creativity, curiosity, learning and research.

I am professionally indebted to the study participants, the data analyst Mr. Kevin Otieno, classmates for the positive peer influence, our wonderful administrators John and Salome, the entire faculty and support team at the Strathmore Business School for the life changing experience.

Finally, I am personally indebted to my loving family for their infinite motivation and grace, without whose support this dissertation would not have been possible.

ABBREVIATIONS AND ACRONYMS

AFCT: Analysis Function Core Team-UK

AI: Artificial Intelligence

BcT: Block Chain Technology

CTPA: Computed Tomography Angiogram

DICOM: Digital Imaging and Communication in Medicine

DL: Deep Learning

DLS: Distributed Ledger System

EHR: Electronic Health Records

Gen AI: Generative Artificial Intelligence

GoK: Government of Kenya

HTA: Health Technology Assessment

ICC: Intra class Correlation Coefficient

IoMT: Internet of Medical Things

ML: Machine Learning

MCDA: Multicriteria Decision Analysis

PACS: Picture Archiving Communications System

PAR: Participatory Action Research

PE: Pulmonary Embolism

WHO: World Health Organization

DEFINITION OF TERMS

Artificial Intelligence: Computational technology mimicking human intelligence. (Dwivedi, 2023).

Computed Tomography Pulmonary Angiography: A radiological imaging mortality specifically used in the detection of Pulmonary Embolism (Nabrawi, 2023).

Efficacy: Ability to produce desired or intended effect (Boverhof, 2024).

Health technology assessment: systematic, evidence informed decision-making tool in the assessment of value proposition from health technologies (WHO W. H., 2023).

Pulmonary Embolism: A blood clot within the lung vascular bed (Kahn, 2022).

Radiology workflow: Used interchangeably with medical imaging workflow in highlighting the pre imaging, imaging and post imaging processes during medical imaging (Pierre, 2023).

Radiologist: Used interchangeably with medical radiologist in identifying medical doctors with specialization in diagnostic and/ or interventional medical imaging procedures (Najjar, 2023)**.**

Radiographer: A trained healthcare professional typically certified or licensed to produce medical imaging (such as X-rays or CT scans) for diagnosis or screening (SORK, 2024).

CT scan technician: A medical radiographer who produces CT scans and manage CT scan machines (SORK, 2024)

CHAPTER 1

INTRODUCTION TO THE STUDY

1.1 Introduction of the chapter

The chapter provides the background of the study, the problem statement, research objectives, significance of the study, scope of the study, limitations of the study and a summary of the chapter.

1.2 Background of the study

Healthcare system building blocks coherently guide non-relational healthcare investments (WHO, 2010). Strategic investments in healthcare respond to complex, dynamic and uncertain health care systems (Huebner, 2022). These building blocks include leadership and governance, service delivery, information, health work force, healthcare financing, medical products/ vaccines and technologies. Healthcare systems have evolved across at least four civilizations over the past few decades (Ahsan, 2022). Healthcare 1.0 was largely limited to providing physical health services such as delivering babies naturally. Modern medicine in healthcare 2.0 added mechanical services like surgery and medical equipment to its repertoire and healthcare 3.0 elevated patient-centric health and healthcare system designs.

Currently, healthcare 4.0 is a data-driven ecosystem enabled by increased connectivity, device miniaturization, data and technological portability. This ecosystem is enacted through Internet of Medical Things (IoMT), cloud computing, big data analytics, cyber physical systems robotics, augmented reality, horizontal-vertical system integration, digital twinning, artificial intelligence (AI) and block chain technology (BcT) (Mwanza, 2023). Mwanza et al systemic review of healthcare 4.0 in Africa highlights its utility in healthcare system, while acknowledging that barriers to optimization are multifactorial. (Mwanza, 2023). They include meagre infrastructure, constrained funding and limited skills (Musa, 2023). This study will assess governance, service delivery, information and technology in understanding the landscape of the fourth industrial revolution in the Kenyan healthcare system.

1.2.1 Artificial intelligence technology

Digitization in healthcare supports multiple and cross functional work flows. Automation and data generation alone does not increase efficiency in service delivery, unless data is mined, cleaned, processed, analyzed and visualized. Healthcare data analytics is a systemic statistical discovery of new information, knowledge management and acquisition of wisdom that drives critical decisions for effective management and improved healthcare delivery (Wan, 2020). Big data utilization therefore infuses a dynamic value proposition which sustains resilient agility when founded on a concrete data strategy (Lugerta, 2018; Muehlbauer, 2022).

Incipient strategic data management by Robert S. Ledley and Lee Browning established theoretical foundations on computerized clinical decision making, diagnosis and therapy after the Turing test in the 1950s (Masic I. , 2014; Najjar, 2023). Seven decades later, technological devolution is supported by, wireless communication, physiological sensor miniaturization, electronic medical records (EHR), connected data repositories and advanced big data analytics. Nascent conception of AI in the 1950s was designed to mimic human problem-solving skills through the logic theorist computer program (Anyoha, 2017; Dwivedi, 2023). In the 1980s, AI algorithmic scope evolved into expert systems modelled on Bayesian statistics and decision theory (Dwivedi, 2023).

AI simulates human intelligence using computational technologies (Dwivedi, 2023). Machine learning (ML) is a subclass of AI where decision making and predictions are automated by human trained AI models while deep learning (DL) is an enhanced subclass of ML that analyzes neural networks without human involvement (Dwivedi, 2023). AI in healthcare spans across at least three epochs (Howell, 2024). AI 1.0 symbolically encodes human knowledge into computational rules and probabilistic models, task specific AI 2.0 develops deep learning models for predictive AI, and transformative generative AI 3.0 multi tasks intrinsically with reinforced learning from old data sets. AI epochs frame the decision pivots for healthcare stakeholders and actors across the healthcare system.

1.2.2 Artificial intelligence in healthcare

The healthcare system burst of activities supporting a delicate omnichannel of medical and administrative operations. Omar et al in a systemic review of more than 1988 articles posits that AI is superior to humans in terms of accuracy, efficiency and timely execution of medical and related administrative processes (Ali O, 2023). AI technologies in healthcare parallel the definition of health in supporting promotive, preventive, diagnostic and rehabilitative health services; physically, socially and mentally (WHO, 2010; Ali O, 2023). Value-added AI in healthcare re engineers' creative IT service delivery models, supply chain management, clinical research, governance, finance, audit & quality management (Mwanza, 2023).

Practical and theoretical aspects of AI remain obscure when clinical translational and the contours of technological autonomy seem undefined in its application (Ali O, 2023). The AI strategy provides a roadmap on how AI initiatives deliver measurable value. Africa`s AI strategy generically scopes the potential socio-economic transformation and cultural renaissance of the technology in Africa (AU, 2024). Kenya is in the process of drafting its own AI strategy which will comprehensively guide how the country harnesses the transformative power of AI ethically (MICDE, 2025). This anchors the policies, tools and framework that will support governance, practice, ethics and the quality of AI technologies in healthcare. The anticipated value of AI in Kenya will be to enhance quality and accessibility of healthcare across the country.

Ali et al proffers an analytical framework for AI in healthcare through four dimensions: Firstly, benefit to the people, the organization and the health care sector; secondly, challenges in data infrastructure, patient attributes and the legal framework; thirdly, methodologies in data and image processing; lastly, functionalities in the clinical ecosystem, patient ecosystem and the sectoral ecosystem (Ali O, 2023). The sectoral ecosystem cream skims AI in medical radiology as the most advance and promising application compared to other medical specialties such as clinical service delivery, biomedical engineering, surgical and interventional procedures. High quality data availability and visual pattern recognition confer standardized technical strengths to radiology compared to its peer medical specialties (Pierre, 2023; Yardanova, 2024).

1.2.3 Artificial intelligence in medical radiology

AI in radiology mimics human intelligence in task automation, rapid learning cycle and big data analytics. Radiology is the fastest growing healthcare specialty in AI innovation and adoption over the past decade (Yardanova, 2024). Literature review of AI in radiology estimates over 200 commercially available AI tools utilized in radiology. Interpretive AI in radiology is applied in lesion detection within the head-neck, heart-blood vessels, lungs, abdomen and musculoskeletal systems in the body (Yardanova, 2024). AI technology can be applied across various radiological imaging modalities including Ultrasound (US) scans, Computed Tomography (CT) scans, Xray scans, Magnetic Resonance Imaging (MRI) scans, nuclear imaging and hybrid scanners (Nabrawi, 2023; Yardanova, 2024).

Non interpretative AI tools do not detect body lesions instead they improve work flows, automate structured reports, assist in image protocoling and scheduling (Yardanova, 2024). Radiology Information System (RIS) is a computer-based system which manages the administrative and clinical workflow (Najjar, 2023). RIS supports the Picture Archiving and Communication System (PACS) as a computer based medical imaging technology which electronically stores, retrieves and displays medical image report from various modalities. Digital Imaging and Communication in Medicine (DICOM) is an international standard for storing, transmitting and communicating radiology related data (Fernandesa, 2022; Pierre, 2023).

Integration of RIS in the diagnostic workflow is more advanced in Europe and North America compared to Africa (Najjar, 2023; Pierre, 2023). Workflow integration is an enabler to AI utilization, as proxy indicator of robust data architecture, radiology infrastructure, advanced technology and skills (Mwanza, 2023). Africa is riddled with healthcare data poverty, meagre infrastructure and limited skills which undermine diffusion of AI in radiology (Kawooya, 2022; Musa, 2023). Kawooya et al contends that this can be circumvented through AI, research and collaboration (Kawooya, 2022). AI application in radiology within Kenya is observed at 12.6% in routine practice with 67.8% willingness to train AI models among radiologists (Mwaniki, 2023).

1.2.4 Health Technology Assessment

Health Technology Assessment (HTA) is a systematic, evidence informed decision-making tool in the adoption of affordable, relevant and cost-effective technologies (WHO W. H., 2023). HTA appraises healthcare priority setting on diagnostic tests, medical devices, medical procedures, medicines and population health interventions against clinical, ethical, economic or social factors. Embedding AI in radiology involves changes in the diagnostic workflow which directly affects business, clinical and operational pathways related to health care delivery. Integration of digital technologies in the healthcare system warrants structured appraisal of its value proposition and sustainability by strategic decision makers (Brady, 2024; Farah*, 2024).

The strategic decision-making apex of AI implementation in radiology is made up of radiographers, radiologist, clinicians and health care managers, with governance support from policy makers and regulators, and knowledge management supported by academicians and researchers (Brady, 2024; Faric, 2024). Co creation of AI enabled radiology with strategic decision makers optimizes task technology fit framed on user centered design (Hua, 2024). Farah et al posits that valuable insights on responsible implementation and maximum benefits of AI technology can be defined using HTA frameworks (Farah*, 2024).

HTA framework guides result comparability across different jurisdictions in policy, decision making and clinical practice (WHO W. H., 2023). A scooping review on the existing HTA frameworks by Farah et al highlights heterogenicity in AI evolution, data requirements, complexity, clinical validation, safety requirements, economic evaluation, regulatory and ethical considerations (Farah*, 2024). Local adaptation is therefore encouraged in defining HTA expertise and contextualizing HTA iterations (Brady, 2024; Farah*, 2024). There is paucity of local frameworks and tools for AI assessment in healthcare within Kenya (KEBS, 2024). The study proposes HTA of AI in radiology within Kenya informed by global standards and considerations (Brady, 2024; Boverhof, 2024; Farah*, 2024).

1.2.5: Decision making in healthcare management

The modern healthcare milieu is intricately intertwined with decision making processes in shaping the contours of excellence and value in healthcare delivery. Healthcare management increasingly operates in a volatile, uncertain, complex and ambiguous (VUCA) environment fueled by advanced technology, shifting labor dynamics, increase in healthcare options, sustainability actuation and a ballooning population (Ahsan, 2022). Transformative healthcare accelerates innovation and information overload which creates demand for cross functional competencies in decision making (Huebner, 2022). Strategic decision-making forms the bedrock of leadership and management in the governance of healthcare systems.

Decision making process in healthcare selects the best alternative based on the available information (Masic I. , 2022). Operational and tactical decision are typically structured while tactical and strategic decisions are typically unstructured (Huebner, 2022). Systems thinking addresses interconnectedness within the healthcare system and the need for multiple perspectives in strategic decision making (WHO, 2010; Huebner, 2022). Multicriteria decision analysis (MCDA) comprehensively guides a structured approach to decision making by systematically evaluating alternatives simultaneously (Gongora-Salazar, 2023). MCDA complements traditional HTA approaches which are limited in comprehensive analysis of multiple attributes and multiple stakeholders.

MCDA combines qualitative elements in exploring stakeholder perspectives and quantitative elements in articulating stakeholder preference and options (AFCT, 2024; Boverhof, 2024). This involves defining the decision problem, selecting the evaluation criteria, assessing the performance scores of each alternative on each criterion, determining the criteria weights, aggregating performance scores and criteria weights in the overall value, dealing with uncertainty, and deliberating over the findings. (Gongora-Salazar, 2023). Rationality in decision making and group decision making is facilitated by MCDA however psychological traps and intuition cannot be fully eliminated in the decision-making process (AFCT, 2024).

1.3 Problem statement

AI innovation in healthcare fuels disruptive tools and technologies at an exponential rate. The attributes of the technology vary from technological/ technical aspects, clinical effectiveness aspects, organizational/institutional aspects, user centered aspects, ethical/ safety aspects, economic and legal aspects (Kristensen, 2017). These multiple attributes favor innovative designs that jointly optimize social, technical and environmental subsystems for responsible and sustainable AI tools and technologies in health care (Kaplan, 2024; Hua, 2024).

Radiology augments clinical care and health system performance in medicine (Alowais, 2023; Hua, 2024; Yardanova, 2024). This is occasionally undermined by human errors, fragmented workflows and user training gaps (Nabrawi, 2023). Literature review on more than 200 AI tools in radiology demonstrate benefits in lesion detection on all imaging modalities while supporting diagnostic workflow and operational excellence. (Yardanova, 2024). Kenya navigates the benefits of AI in radiology through independent and collaborative initiatives. The process is however dysregulated, opaque and fragmented due to a dearth in clarity of its value proposition, since technology commonly outpaces regulation in healthcare (MICDE, 2025).

HTA supports generic evaluation and standardizations of software as a medical device (Farah*, 2024). Positional statement from Asian Oceanian society of radiology on adoption and implementation of AI in radiology is limited to bioethical consideration. Multi society considerations (MSC) from radiologists in USA, Canada, Europe, Australia, and New Zealand propose practical considerations in the development, purchase, implementation and monitoring of AI tools in radiology (Brady, 2024). Boverhof et al propose the radiology AI deployment and assessment rubric (RADAR) for the valuation of radiology AI from conception to local implementation (Boverhof, 2024). Kenya needs its own framework aligned to the local AI strategy so as to impute its value attributes drawn from global considerations.

There is literature gap on comprehensive HTA considerations from Africa and Kenya on AI in radiology (Kawooya, 2022; Mwaniki, 2023). HTA is not a linear knowledge product, its heterogenicity draws perspectives from different stakeholders, technologies, people, processes and information. Rationale and group decision making summons multi criteria decision analysis in accommodating diverse stakeholder perspectives despite nuanced influences from psychological traps and intuition-based decision making (Martelli, 2016; AFCT, 2024). HTA standardization supports credibility, acceptance and comprehensive value assessment of AI in radiology among multiple decision makers, across multiple attributes, against global evidence (AFCT, 2024; Farah*, 2024).

1.4 Research Objectives

1.4.1 General Objective

The general objective of the study was to develop a health technology assessment tool for artificial intelligence in radiology within Kenya.

1.4.2 Specific Objectives

1. To assess artificial intelligence in radiology using radiology multi-society practical considerations.
2. To assess artificial intelligence in radiology using the radiology AI deployment and assessment rubric.
3. To evaluate health technology assessment of artificial intelligence in radiology through multicriteria decision analysis.

1.5 Research questions

1.5.1 General research question

Can a health technology assessment tool for artificial intelligence in radiology be developed in Kenya?

1.5.2. Specific research questions

1. Can radiology multi society practical consideration assess artificial intelligence in radiology?
2. Can radiology AI deployment and assessment rubric assess artificial intelligence in radiology?
3. Can health technology assessment in artificial intelligence in radiology be evaluated using multicriteria decision analysis?

1.6 Significance of the Study

Digital inclusion and knowledge management of AI in healthcare continues to lag behind in Sub Saharan Africa limiting its innovative potential. Technology commonly outpaces regulation hence the need for a structured appraisal on value proposition. Findings from this study will inform the adoption of AI as a medical device, co-created by strategic decision makers in the development and deployment of AI in radiology. This provides a foundation for responsible, ethical, equitable and sustainable AI investments in radiology within Kenya.

1.7 Scope of the study

This study principally proposes a health technology assessment tool for AI in radiology within Kenya. The tool was primed by radiology multi society practical consideration and the radiology AI deployment and assessment rubric. The hypothetical application case was an AI enabled lesion detection software of pulmonary embolism on computed tomography pulmonary angiogram images. Geographically, the assessment was performed among Kenyan experts. Theoretically, this research was nested within the socio technical system theory supported by the Health Technology Assessment model 3.0. Methodologically, this was an action research designed to propose the development and implementation of a health technology assessment tool for AI in radiology among strategic decision makers through multicriteria decision analysis.

1.8 Limitations of the study

The AI software was a hypothetical illustration of lesion detection software on radiology images. This widens the AI chasm in the adoption cycle when translating hypothetical illustrations to real illustrations. However, baseline research provides incipient market intelligence in the development and deployment of AI in radiology while de risking the capital requirements for full integration of AI in a standard radiology workflow.

1.9 Summary

Healthcare data analytics supports data driven decisions. Complex and inefficient diagnostic workflows can be improved through AI in radiology. This is however complicated by information overload and rapid technological advancement of AI in radiology. Multi criteria decision analysis of health technology assessment by strategic decision makers improves rationality in group decision making process. This study proposes a standardized and credible HTA tool for AI in radiology within Kenya.

CHAPTER 2

LITERATURE REVIEW OF THE STUDY

2.1 Introduction of the chapter

This chapter posits an anchor theory and the supportive model, it interrogates relevant literature and research gaps, operationalizes the research variables and the conceptual framework.

2.2 Theoretical Review

This section fronts the socio technical systems theory supported by health technology assessment model 3.0 in HTA assessment of AI in radiology.

2.2.1 Socio technical theory

Socio technical theory (STS) was developed in 1951 by Eric Trist and Fred Emery at the Tavistock Institute in London (Ropohl, 1999). STS highlights reciprocity in designing hybrid socio-technical systems (Feng, 2022). It operates in three sub-systems. Social; related to human factors, Technical; related to tools and skills, and Environmental; related to internal and external organizational context (Abbas, 2023). Socio technical design underscores the people and the technology in joint optimization, equifinality and multi-dimensionality in curating agile and innovative open system (Abbas, 2023).

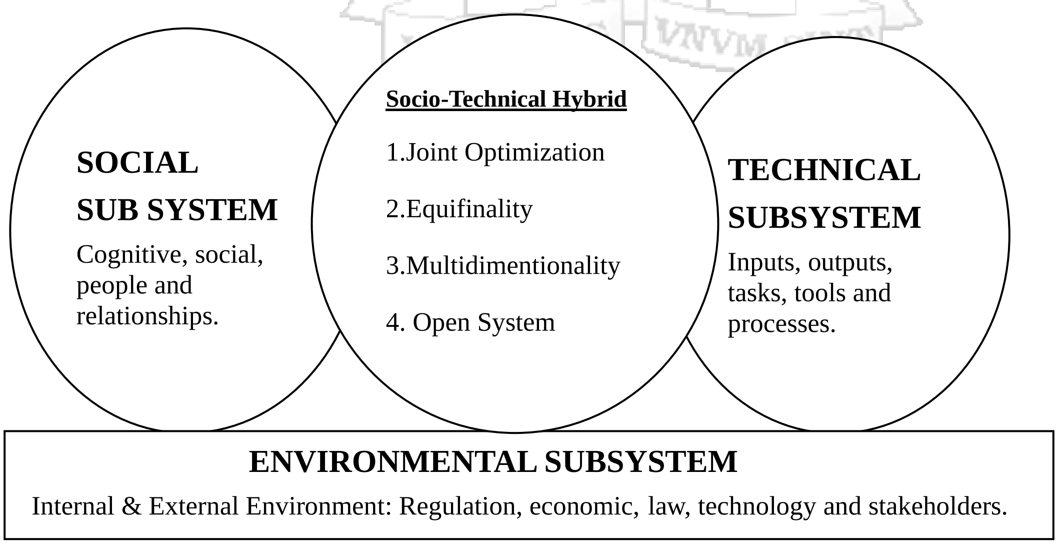

Figure 2.1 Social Technical Subsystems illustration (Source; Author, 2024)

STS focuses on the interactions between the people, the technology and the environment in expressing the socio-technical fit within the three subsystems. This study looks at the generic appraisal of AI attributes in radiology which favors STS as a generic theoretical anchor (Abbas, 2023). The diffusion of innovation theory interrogates how technology spreads informing user acceptance while STS actuates how innovation interacts with the system informing systemic design for successful implementation. (El Malouf, 2023; Abbas, 2023). Ethics, equity, cost and evaluation theories are also limited in scope based on the technological attributes the study is evaluating (Farah, 2023).

Despite its broad application, STS has been criticized on slow adaptation to technological change due to over emphasis on human centric design (Abbas, 2023). This flaw is more prominent in non-clinical AI technologies however, clinical AI favors AI-human augmentation as a safety valve to safe and ethical medical AI (Hua, 2024). Lack of clear implementation guidelines and difficulties in measuring clear outcomes stifles commitment to the Kenyan AI strategy and value translation in design, implementation and deployment of AI in radiology (Abbas, 2023; MICDE, 2025). This informs the need of a supportive model that clarifies implementation guidelines as well as measurable outcomes for AI in radiology i.e. HTA core model 3.0.

2.2.2: HTA Core Model 3.0

HTA model was developed between 2006-2008 as an international framework for multi-dimensional value assessment of healthcare technologies (Kristensen, 2017). The model was developed by more than 70 institutions and can be applied globally within the international, national and local contexts. The model has undergone several iterations with the latest revision; HTA core model 3.0 supported by the European union. It commissions multidisciplinary, comprehensive or limited HTA, done either early or late in the lifespan of the technology. Value frameworks vary across healthcare pathways and decision makers, therefore standardization of structures and interventions across a shared repository communicates credible and contextualized global evidence while reducing duplicity.

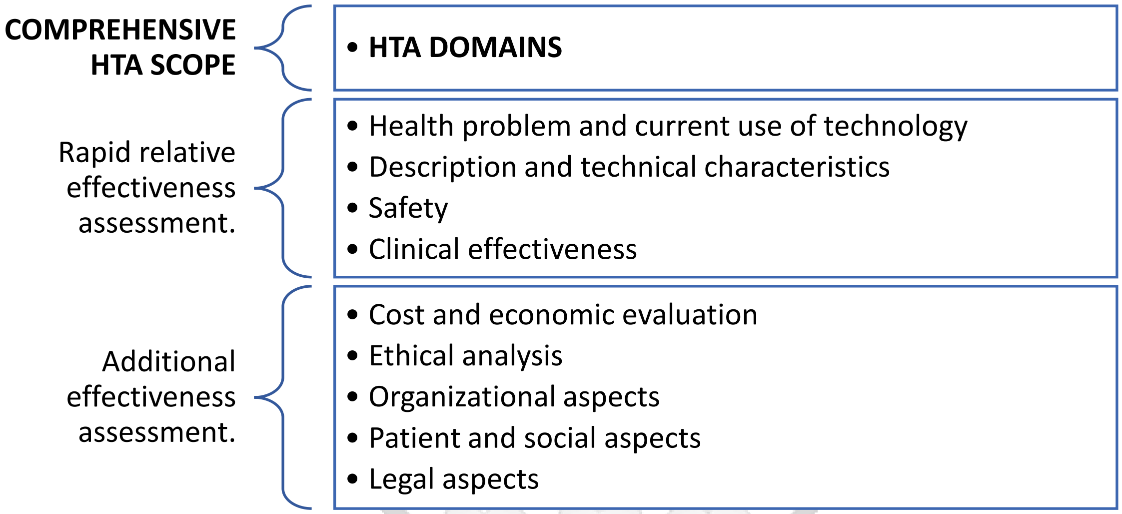

Figure 2.2: HTA core model domains and scope, Source: (Farah, 2023)

The generic model undergoes continuous revision which allows for flexibility responsive to user needs in domain scope, application and decision support systems. The model provides HTA domains for AI technologies which lack explicit reference (Ferizovik, 2022). Farah et al in a systemic review further posits lack of comparability in HTA evaluations for AI medical devices across jurisdictions calling for research on novel suitable approaches (Farah*, 2024).

2.2.3 Application of the theory and the model

STS is founded on the concepts of; joint optimization based on the degree of fit in the social technical system, equifinality alluding to multiple successful design options of the system producing the same outcome, open system view alluding to reciprocity in the interaction between the environment and the organization/ institution and multi dimensionality predicating multiple perspectives in assessing the system which has multiple attribute as seen in the HTA core model domains 3.0 (Abbas, 2023; Farah, 2023).

HTA core models 3.0 provides a decision-making framework against patient attributes, organizational attributes, ethical/safety attributes, technical attributes, cost/economic attributes and healthcare rationale attributes. (Farah, 2023). Decision making analytical models provide a formal approach to the process for optimal decision making despite uncertainty (Martelli, 2016; AFCT, 2024). Multicriteria decision analysis (MCDA) reflects progression in decision and management science from the foundational principles of mathematical decision making in the 1940s to computational decision-making models in the 2000s (Masic I. , 2014; Gongora-Salazar, 2023). Four main blocks of activity in the MCDA processes are; to structure the problem, establish options and performance, elicit preferences of the decision stakeholders and review the input (AFCT, 2024).

This study explores multidimensionality as a concept within the social technical theory in the health technology assessment of AI in radiology. The assessment was statistically validated using multicriteria decision analysis of perspectives from strategic decision makers. Environmental subsystem factors were deduced from legal, cost and economic attributes. Technical subsystems were deduced from current use of the technological and technical characteristics. Social subsystems were deduced form patient and social attributes.

Social technical theory **HTA core model 3.0 domains**

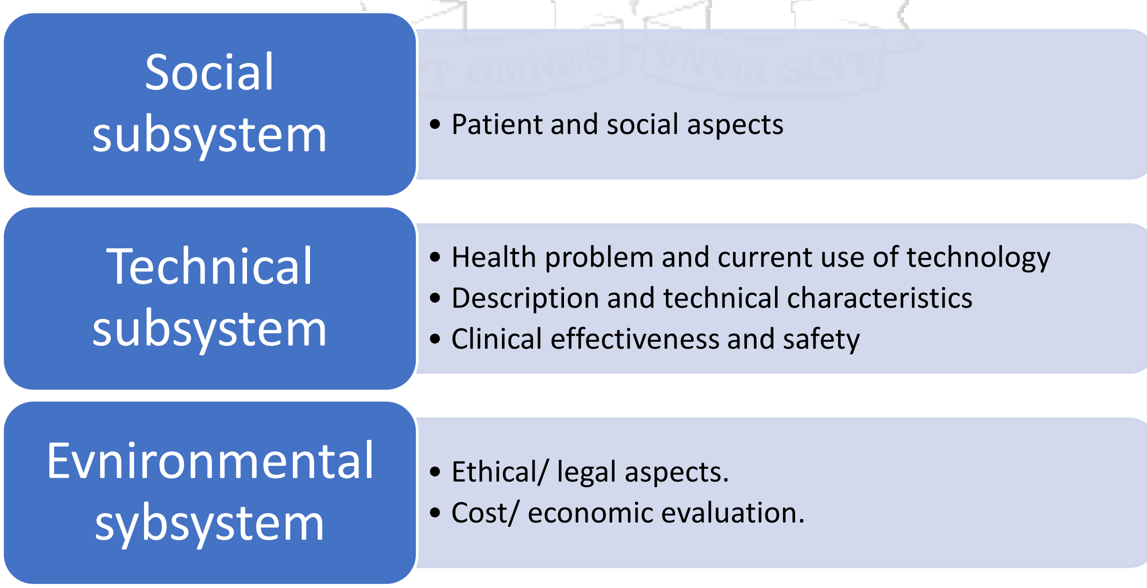

Figure 2.3: Interaction between STS subsystems and HTA domains (Source, Author 2024)

2.3 Empirical review

Evidentiary value of the objectives was assessed on radiology and AI in Kenya.

2.3.1 Radiology and AI in Kenya

Radiologists are consultative partners whose insights directly influence patient care. Multi society statement from radiologists globally put forward value-based radiology as a concept defining their value in healthcare (European Society of radiology, 2021). Radiology practice is transitioning from value defined in clinical, academic and financial productivity to patient outcome and societal benefit (European Society of radiology, 2021). This global position does not feature Africa and Asia. However, Wee et al focused on bioethical principles in value delivery within Asia (Wee, 2024) while Kawooya et al focused-on quality and safety in value delivery within Africa (Kawooya, 2022). They argue that patient centered value delivery remains a distant milestone unless stakeholder collaboration and ethical AI technologies are marshalled in closing the gap.

AI enabled radiology has been rigorously evaluated on diagnostic performance with little attention to comprehensive assessment before clinical translation (Cheikh, 2022; Kahraman, 2023; Ul Islam, 2024). Incipient studies in assessment of AI in healthcare are quite heterogenous advocating for local adaptation given contextual variations (Boverhof, 2024; Brady, 2024; Farah*, 2024). Maturity of AI in radiology is at best in the exploratory phase in development, regulation, assessment and clinical application within Kenya (Mwaniki, 2023; Castonguay, 2024). Decision makers in the implementation of patient centered radiology within Kenya are commonly radiologist, radiographers, clinical care providers and healthcare managers.

Kenya is finalizing on its AI strategy (MICDE, 2025), the strategy is supported by the Health Act 2017 (GoK*, 2022) Data Protection Act of 2019 (GoK`, 2019) and the Digital Health Act of 2023 (GoK', 2023) in regulating health technologies and digital health services in Kenya. Software as a Medical Device (SaMD) is registered and licensed by the Kenya Pharmacy and Poisons Board provisioned by the Pharmacy and Poisons Act 244 (GoK., 2012) with governance on AI code of practice by the Kenya Bureau of Standards (KEBS, 2024). Despite significant exploration on SaMD in radiology locally, there is a gap in published reports regarding comprehensive HTA frameworks on AI and AI radiology within Kenya.

2.3. Radiology multi society practical considerations on AI (MSC)

Organizational readiness and impact of AI can be measured in terms of stakeholder acceptance, organization alignment and financial business plan (Farah*, 2024). Brady et al give a multisociety account on practical considerations during development, purchase, implementation and monitoring of AI tools in Radiology (Brady, 2024). The multi-society representatives drawn from the American College of Radiology (ACR), Canadian Association of Radiologists (CAR), European Society of Radiology (ESR), Royal Australian and New Zealand College of Radiologists (RANZCR), and Radiological Society of North America (RSNA) define user considerations when appraising AI value in clinical practise and regulation.

Regulator conformity does not guarantee successful implementation of AI into the workflow. The intended use, benefit , risk and cost of AI form baseline considerations in justifying AI adoption in radiology (Farah, 2023). These considerations form strategic objectives aligned to the expected institutional performance. Performance can be linked to cost reduction, innovation, quality & safety, or competitive advantage (Brady, 2024). Specific objectives reduce ambiguity in measurement while safeguarding explainability and deployment (Abbasian, 2024). These objectives inform software costs, vendor compatibility and digital adaptation kits.Software performance and bias are the biggest direct risk to clinical effectiveness. This can be cured by radiologist led AI augmentation, provided that deskilling is prophylactically addressed (Brady, 2024).

Domain experts in radiology practise are the bioethical gatekeepers, AI model validation yardsticks and detectors of model drift in the software development cycle (Brady, 2024). Medical ethics based on non maleficence, beneficience, justice and autonomy sign post universal bioethical principles in healthcare (Brady, 2024). User behavior, attitude and intention should therefore be incooperated in the design and development on AI as enablers and barriers to diffusion of AI in radiology (Hua, 2024; Kaplan, 2024). Adoption apathy, increased error rates and lack of trust are un intended consequences of user dissatisfaction with AI design (Farah, 2023).

2.3.4 Radiology AI deployment and assessment (RADAR) rubric

Radiology AI deployment Assessment Rubric (RADAR) is an adaptation of Fryback and Thornbury's imaging efficacy framework designed to evaluate contribution of diagnostic imaging to a patient management process (Fryback, 1991). RADAR progresses through seven hierarchical levels of efficacy, each step forming a rate limiting step to the next (Boverhof, 2024). The rubric attributes include; RADAR-1 technical efficacy, RADAR-2 diagnostic accuracy efficacy, RADAR -3 diagnostic thinking, RADAR-4 therapeutic process, RADAR-5 actual patient outcomes, RADAR-6 cost effectiveness efficacy and RADAR -7 local efficacy. RADAR 1& 2 are foundational measures which predominantly assess clinical implementation. Radar 3,4 & 5 zone in on actual patient outcomes and RADAR 6 &7 assess technological socio-economic factors.

RADAR1-5 measures clinical value without temporal specification i.e. prospective clinical solutions vis retrospective proof of concept. Valuation methodology can be cohort, cross sectional, randomized control trial or virtual trials, based on the priority in the valuation and tradeoffs in appraisal of the software (Boverhof, 2024). This was a prospective evaluation of a hypothetical AI lesion detection software. It taps into the rubrics dynamic design to meet diverse needs throughout the model's lifecycle.

RADAR 6 &7 evaluates AI model beyond clinical value. Health economic evaluations inform the financial feasibility of AI in medical imaging which is generally scarce. Cost analysis measures the cost of AI against clinical outcomes (Boverhof, 2024). Budget impact analysis contextualizes local budgetary constraints and population composition in discerning affordability and sustainability of AI in radiology (Boverhof, 2024; Farah*, 2024). Multi criteria decision analysis weighted against contextual priorities provides rationality in optimizing socio technical fit informed by propositions from strategic decision makers.

2.4 Research gaps

The following section outlines the knowledge, contextual and methodological gaps filled by the research objectives. The gaps were derived from three main studies in health technology assessment of AI in radiology

Table 2.1: Research gaps (Source: Author, 2024**)**

Authors	**Title**	**Findings**	**Research gap**
Brady, A.P., Allen B., Chong J., Kotter E., Kottler N., Mongan J et al (2024)	Developing, Purchasing, Implementing and Monitoring AI tools in radiology	Radiologists' multi-society practical considerations during development, purchase, implementation and monitoring of AI tools in Radiology Expert opinion	Contextual, knowledge and methodological gap on considerations for HTA of AI in radiology
Boverhof, B-J., Redekop W.K., Bos D., Starmans M.P.A., Birch J., Rockall A and Visser J.J. (2024)	Radiology AI Deployment and Assessment Rubric (RADAR) to bring value-based AI into radiology practice	Valuation of AI in radiology from conception to local implementation	Contextual, knowledge methodological gap on HTA on AI in radiology
Farah, L., Bourgete I., Martelli A and Vallee N (2024)	Suitability of the Current Health Technology Assessment of Innovative Artificial Intelligence-Based Medical Devices: Scoping Literature Review	A comprehensive adapted HTA framework for AI-based medical devices can guides on responsible of AI	Contextual, knowledge, methodological gap on HTA assessment of AI in radiology using HTA core domains.

2.5 Conceptual Framework

The conceptual framework is a conjecture model for assessment of AI in radiology before implementation.

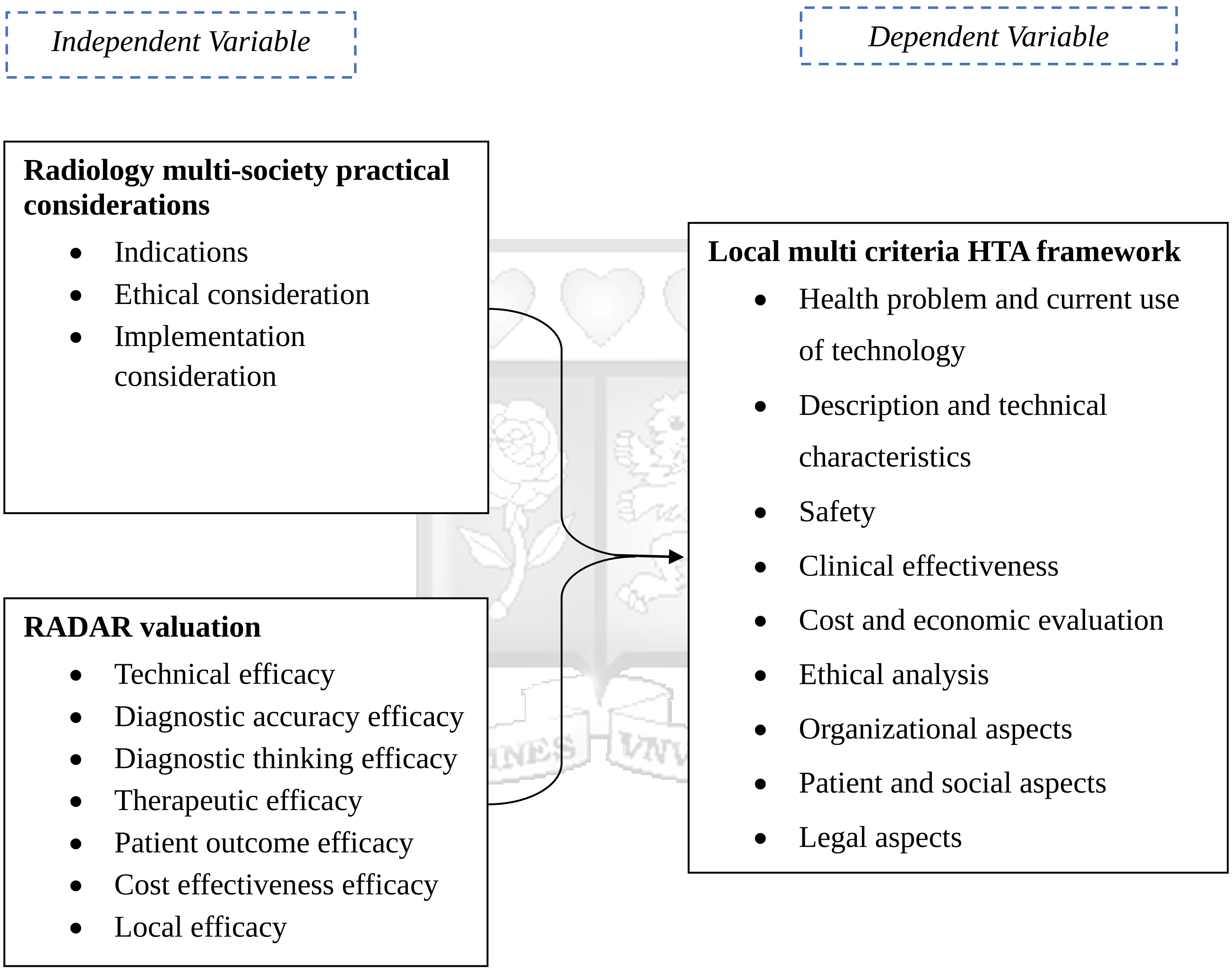

Figure 2.3: Conceptual framework (Source: Author, 2024)

2.6 Operationalization of variables

Variables under study were measured as indicated in table 2.2 against the specific objectives.

Table 2.2: Operationalization of variables (Source: Author,2024)

Measurement	Variables	Data Collection Instrument	Citation
Objective 1: Radiology multi-society practical considerations	Indications Ethical consideration Implementation consideration	Check list	(Brady, 2024)
Objective 2: RADAR rubric	Technical efficacy Diagnostic accuracy efficacy Diagnostic thinking efficacy Therapeutic efficacy Patient outcome efficacy Cost effectiveness efficacy Local efficacy	Check list	(Boverhof, 2024)
Objective 3: HTA core domains 3.0 multi criteria decision analysis	Health problem and current use of technology Description and technical characteristics Safety Clinical effectiveness Cost and economic evaluation Ethical analysis Organizational aspects Patient and social aspects Legal aspects	Work book sheets	(Martelli, 2016; Kristensen, 2017)

Independent variables were derived from the multi society considerations and the RADAR rubric while dependent variables were derived from the HTA core domains 3.0 (Boverhof, 2024; Brady, 2024; Farah*, 2024). Deductive thematic measurements were calibrated against a 3 Likert ordinal scale. Participants were asked to score perceived indications, bioethical consideration and implementation considerations (Appendix III). The RADAR valuation tool was evaluated against technical efficacy, diagnostic accuracy efficacy, diagnostic thinking efficacy, therapeutic efficacy, patient outcome efficacy, cost effectiveness efficacy, local efficacy (Appendix IV).

2.7 Summary

Socio technical systems theory supported by HTA core model 3.0 proposed a local HTA framework derived from existing considerations and RADAR rubric through contributory action research. Rationality in group decision making was documented through multicriteria decision analysis of expert opinions from strategic decision makers on implementation of AI in radiology.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Introduction to the chapter

This chapter describes the research philosophy, research paradigm, research design, sample size, sampling, data collection methods, data analysis and ethical considerations of the study.

3.2 Research Philosophy

The research philosophy fronted a set of basic beliefs which guided the design and execution of the study in addressing knowledge creation. It grounded the research strategy since the research process was based on assumptions. The study applied both the positivism philosophical approach and the social constructivism philosophy. The positivism philosophical approach assumed objectivity in dissociating personal values from the research process using deductive themes for the study. The social constructivism philosophy assumed that reality constructs were influenced by social interactions through decision making based on expert opinions (Dawadi, 2021; Saunders, 2023). Both philosophies allowed for joint optimization in proposing a HTA tool for AI in radiology within Kenya.

3.3 Research paradigm

The research paradigm fronts the authors assumption's in conducting research. Three pillars of the research paradigms were explored (Dawadi, 2021; Saunders, 2023). Ontologically the research explored multiple realities where co creation of the tool had inputs from decision makers as well as established frameworks of reference. Epistemologically knowledge and reality validation were underpinned on deductive themes, rationale decision analysis and inferential statistical validation. The axiology pillar was defined by ethical principles and guidelines as stipulated by ethical research committee and practiced by the researcher/research team. Validity, reliability, and ethical principles were employed in safeguarding research quality, objectivity and ethics.

3.4 Research design

The research design outlined a framework through which the researcher gathered & presented research findings. This was action research which transformed abstract thoughts from rhetoric into practical application through knowledge co creation iteratively (Shani, 2019). Action research suitably provides a research strategy in designing agile and sustainable systems for rapidly changing and emerging technologies in strategic healthcare management (Saunders, 2023).

Major activities in the action research cycle included; planning the action, taking action, evaluating the action and adopting or rejecting the action (Saunders, 2023). This study proposes a HTA tool for AI in radiology, using deductive themes from the radiology professional multi society considerations and the RADAR rubric (Boverhof, 2024; Brady, 2024). Domain experts and decision makers iteratively proposed an assessment tool anchored on the HTA core model 3.0 which provides a global reference framework (Farah*, 2024).

3.5 Target population

The target population focused on medical doctors and radiographers with one or more roles in the healthcare system. They inform strategic decision on AI in radiology as radiologist/radiographers, healthcare managers/clinical providers. The study invited expert opinions from digital health experts, healthcare policy makers and participants in healthcare academia and research. HTA in radiology and implementation of AI in radiology is a relatively new and evolving concept hence the target population is expected to be small. A proxy indicator study by Mwaniki et al among radiologists indicated that almost 40% are not willing to integrate AI in Radiology with concerns on job security (Mwaniki, 2023).

3.6 Sample size and sampling procedure

Action research explores interorganizational dynamics expressed through appreciative inquiry and collaborative management research. Quality of the relationships depicting richness and impact informed a purposive multi stage sampling of approach guided by stakeholder representation and thematic saturation (Shani, 2019). Three domain experts recruited from the Kenya Association of Radiologist (KAR), the Society of Radiographers in Kenya (SORK), the Kenya Medical Practitioners and Dentist Council (KMPDC) and the Non-Clinical Doctors (NCD) group were invited to validate the tool.

The tool iterations were shared with strategic decision makers through professional on-line platforms. Data was collected from 54 respondents which fulfilled the proposed statistical validation of the respondents qualitatively. (Rahimi, 2024). Quantitative validation of the data through parametric tests was also feasible since the central limit theorem of 30 respondents was exceeded (White, 2023).

3.7 Eligibility criteria

3.7.1 Inclusion criteria

- Medical doctors in clinical practice e.g. radiologists, generalists and specialists
- Medical doctors in non-clinical practice e.g. digital health practitioners, policy makers, healthcare managers and academic/ research practitioners
- Radiographers in clinical and non-clinical practice.
- CT scan technicians

3.7.2 Exclusion criteria

- Non-English-speaking participants
- Participants not familiar with the CT scan radiology diagnostic workflow.

3.7 Data Collection

Permission was sought from both the Strathmore University Ethical Research Committee (SU-SERC) and the National Commission for Science Technology and Innovation (NACOSTI). Written informed consent was also sought from all the respondents (Appendix I &II). Data was collected electronically between July, 24 and September, 24. The original tool developed by the researcher was validated by three domain experts (DE); a radiographer, a radiologist and a health care manager who is also a medical doctor with more than five years of experience in clinical practice.

The DE were practicing actively in tertiary facilities with infrastructure and capacity to detect pulmonary embolism on CT scan images. They filled a check list derived from the Multi society practical considerations and RADAR rubric (Appendix III). The1st iteration was done within one week in July, 24 by the three DE. 2nd iteration was done within 1 week in July, 24 by the three DE and final questionnaire was filled between August and September, 24 by the fifty-four decision makers (DM). The link was closed on 3rd Oct, 24. Data completion, validity and iterations were confirmed by the researcher and mined on to spreadsheet for analysis.

3.8 Data Analysis

Descriptive analytics were presented as proportions and visualized as bar graphs, radar charts and pie charts. The first three iterations were done through sequential elimination and multicriteria decision analysis (MCDA). MCDA complements HTA in making structured and transparent decisions (Martelli, 2016) through a series of steps in figure 3.1 (Gongora-Salazar, 2023).

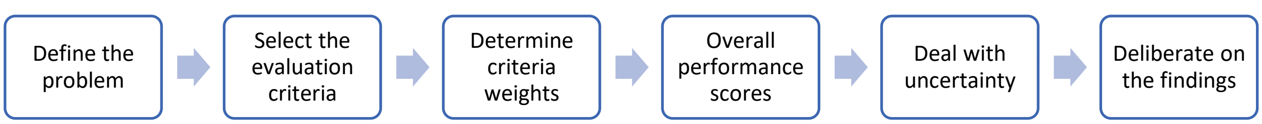

Figure 3.1: Steps in multicriteria decision analysis (Source: Researcher, 2024)

The problem was to decide on the HTA items. The evaluation criteria were provided by the multi society considerations and the RADAR rubric. Criteria weights were assigned based on expert opinion from decision makers with direct rating of the scores against a 3 Likert ordinal scale.

Parameter uncertainty was addressed through statistical validation of final tool on SPSS v25 and deliberations presented as the final HTA tool.

3.8 Research quality

Reliability and validity of research cleped as the scientific canons of inquiry by Saunders, are central to credibility in research (Saunders, 2023). The quality and integrity of the study will be safeguarded through measures of validity and reliability in developing objective metrics of the study as follows.

3.8.1 Measures of reliability

Reliability appraises consistency (Saunders, 2023). Stakeholder validation may not allow for result generalization however the tool allows for contextual validation in low resource set up where AI in radiology is at the exploratory phase and HTA tools are not explicit. Psychological traps and intuition were partly addressed using deductive themes which are objective. Deductive themes were statistically validated using the Cronbach alpha intraclass correlation co efficient which ranges between 0-1, where acceptable reliability is represented by $\alpha > 0.7$ (Ranganathan, 2024).

3.8.2 Measures of Validity

Validity appropriates measures of generalizability; it appraises data relevance and accuracy. Internal validity checks on reproducibility/credibility of the study while external validity checks on generalizability of the study (Saunders, 2023). The tool was initially validated among the three domain experts for face, content, construct and criterion validity. Threats to internal validity of the tool were addressed through iterations of the tool using action research. Construct and criterion validity were reinforced in further iterations and statistical validation of the local HTA tool (Ranganathan, 2024).

3.9 Ethical Considerations

The main ethical issues in the study revolved around data handling, transfer, privacy and data protection. Ethical principles were applied by ensuring academic and scientific soundness of the research. The study was approved by the Strathmore Scientific Ethical Review Committee (SU-ISERC) ref no. SU-ISERC2327/24 and NACOSTI license no: NACOSTI/P/24/38065. Written informed consent from participants was sought and participants freely opted out without any consequence. (Appendix I&II) Data was de - identified after mining and confidentiality was enforced through rights control and password protected spread sheets.

3.10 Summary

Positivism and social constructivism philosophical approach of the study ontologically explored multiple realities, epistemologically modelled through action research, analyzed using multi decision criteria analysis and axiologically supported by the ethical review and statistical validation process. The research design facilitated co creation of HTA of AI in radiology in a low resource setup where HTA tools are not explicit.

CHAPTER 4

PRESENTATION OF RESEARCH FINDINGS

4.1 Introduction to the chapter

This chapter describes participants in the study, iterations on the tools and proposes the final tool.

Participants profile

Fifty-four medical doctors and radiographers participated in the study representing decision makers on the implementation of AI in radiology. Most participants had practiced for more than 10 years however most radiologists and radiographers had been practitioners for less than 10 years as demonstrated in Figure 4.1 below.

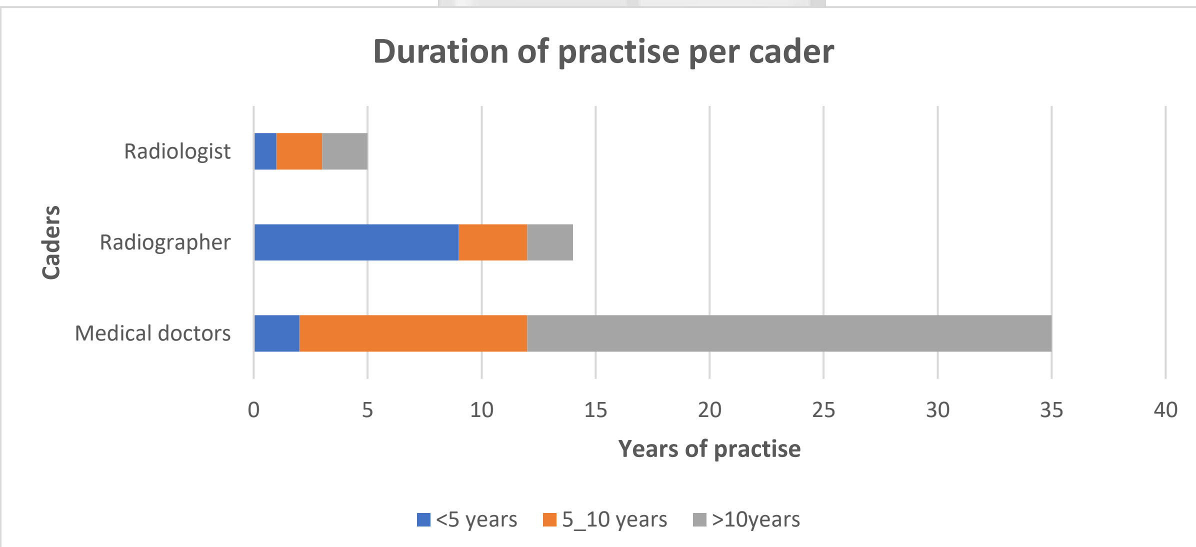

Figure 4.1: Frequency of practice duration among medical doctors and radiographers.

(Source: Researcher, 2024)

Radiographers use AI in radiology more frequently than radiologist as shown in figure 4.2. There was no inquiry on the use of AI in radiology among the other cadres since the hypothetical use case was an explicit radiological competence reserved for radiologists and radiographers.

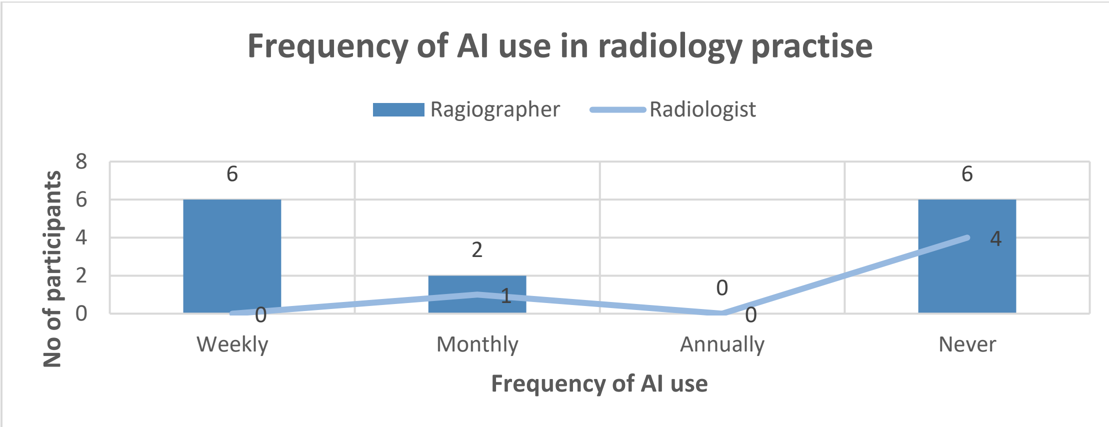

Figure 4.2 Frequency of AI use in radiology (Source: Researcher, 2024)

All participants were either medical doctors or radiographers with additional predominant practice in policy/regulation, digital health, academics/research or administration/management. Digital health, policy/regulation practitioners were least represented compared to the other cadres as shown in figure 4.3

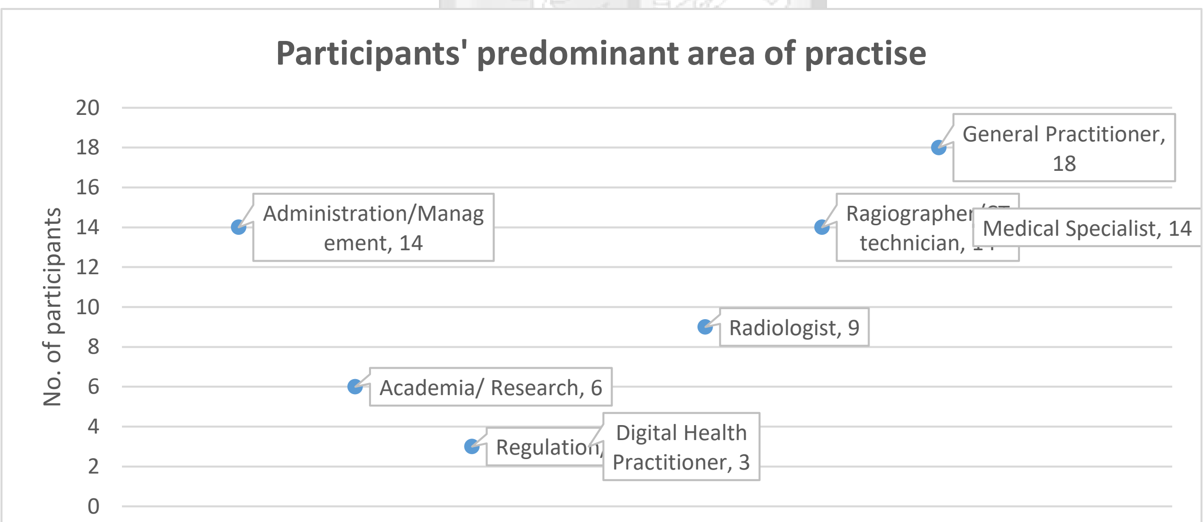

Figure 4.3: Number of participants across predominant areas of practice (Source: Author, 2024)

4.3 Stakeholder preference iterations

Stakeholder preference was defined by three domain experts (DE). DE were requested to rank 66 items on the original tool as high (to retain the item in the next iteration), moderate (items can be retained or removed in the next iteration) or low (item should be removed in the next iteration). (Appendix III &IV). Agreement to retain any item in the subsequent iteration was defined by DE consensus in the ranking across each item. DE expressed that the hypothetical AI application is of moderate to high complexity and recommended a 3 Likert scale for ease of use as opposed to 5 or7 Likert scales.

The first iteration demonstrated an interrater agreement of 0.94 where 26 items were removed and three items with similar constructs were merged by DE. Considerations on long term stability of the model and human AI interaction had the highest dissent. DE felt AI is rapidly evolving and long-term plans will be obsolete. The amended tool was shared once more with the DE for the second iteration and an inter-rater agreement of 0.98 was demonstrated where 1 item was removed (Appendix V).

4.4 Multicriteria decision analysis

Multicriteria decision analysis (MCDA) was applied on the third iteration of stakeholder preference among 54 decision makers (DM). The decision problem was to validate multi society considerations and the RADAR rubric which forms the evaluation criteria. Performance was scored against a 3 Likert scale where decision maker preference was scored as high, moderate or low for each item.

Multi society considerations as an evaluation criterion was ranked by decision makers against an ordinal scale. Majority of the DM preferred items from the third iteration. The highest indication for AI was clinical benefit (47;87%) and clinical risk management (46;85%). Fairness (33;61%) had the least consideration as a bioethical principle and DM considered peer recommendation moderately (22;41%) in the implementation of AI I radiology.

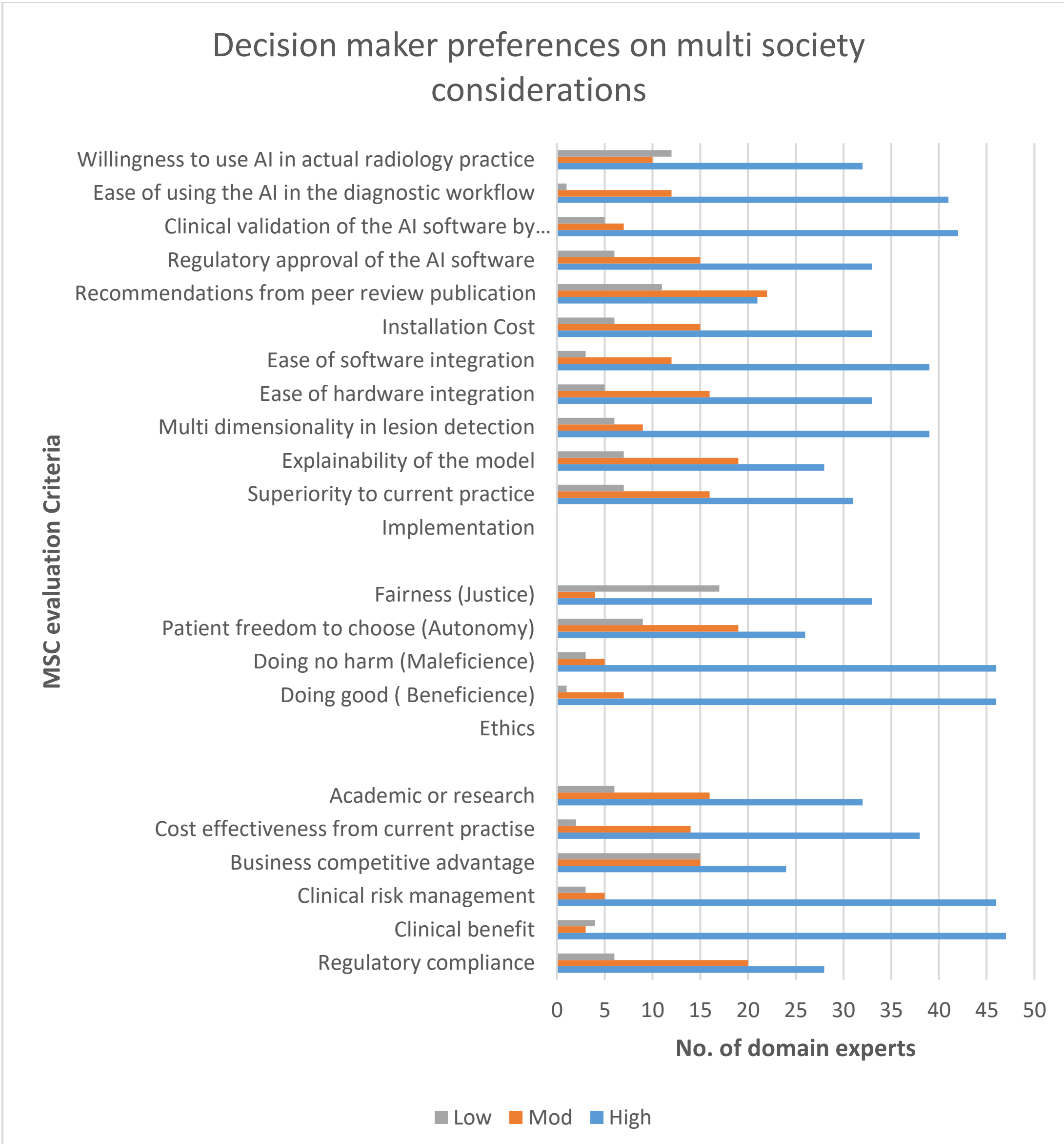

Figure 4.4: Decision maker preferences on multi-society considerations (Source: Author, 24)

Evaluation criteria proposed by the RADAR rubric was also ranked by decision makers against an ordinal scale and majority of the decision makers ranked the items as high (Figure 4.5). The highest DM preference was on explainability of the results as a technical capacity (45;83%), ability to detect lesion as a diagnostic capacity (43;80%), and impact on patient outcomes as a contribution to patient management (41;76%). Most DEs assigned moderate scores to usefulness of AI results (21;39%) and actionable insights from AI results (22;41%). Affordability of AI implementation was least ranked on cost effectiveness of AI implementation (14;26%).

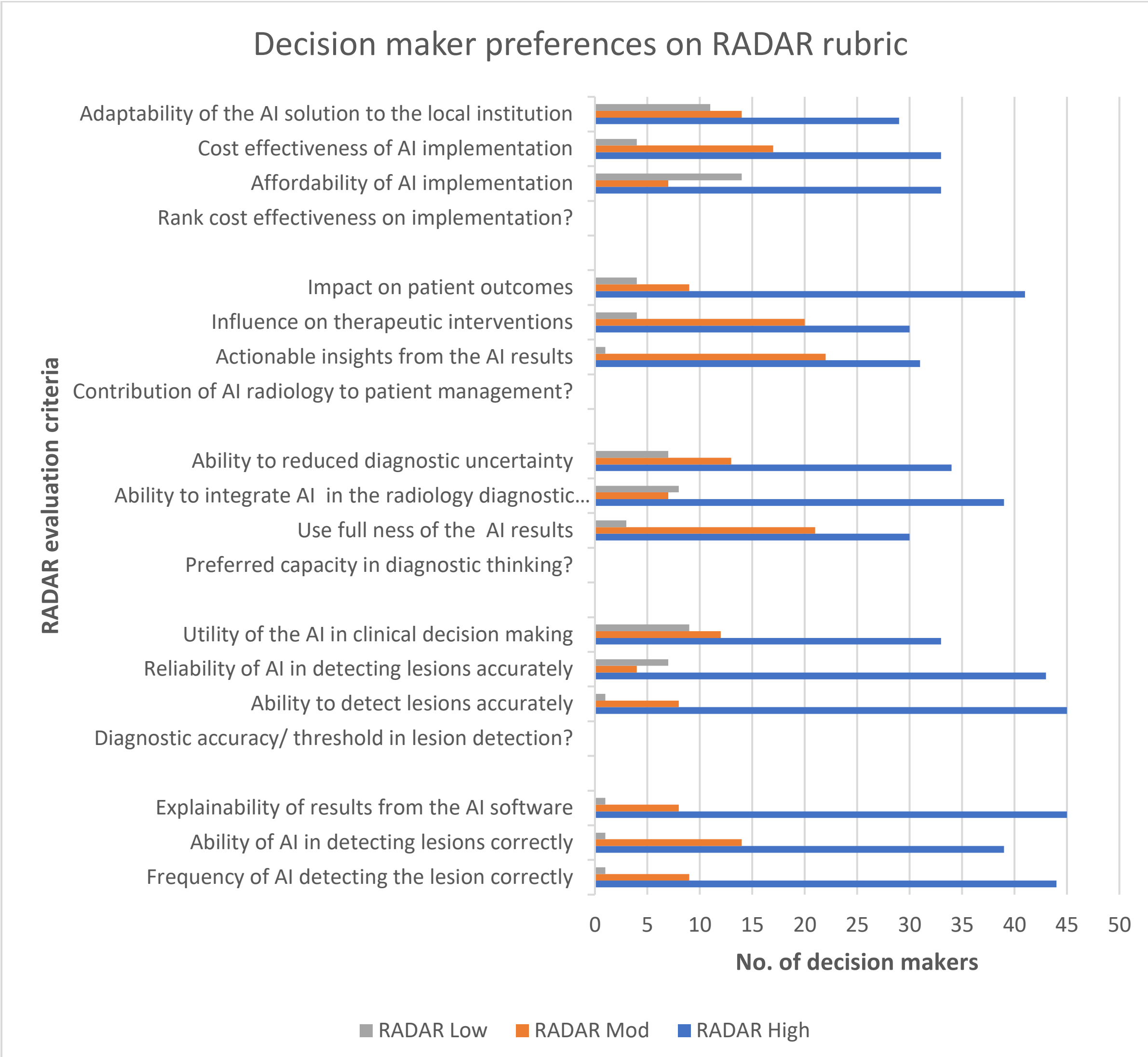

Figure 4.5: Decision maker preference on RADAR rubric (Source: Author, 2024)

The performance of each alternative criterion was weighted on a 3 Likert scale tool with overall performance shown in figure 4.4 and figure 4.5. Deductive themes/ items on the tools were not aggregated to preserve the construct of the items so that no item is lost in translation.

4.5 Reliability of the tool

Intra-class correlation coefficient (ICC) was calculated on SPSS v25 using Cronbach alpha for MSC and RADAR rubric showing a significant ($p<0.001$) acceptable reliability >0.7 with good agreement for most deductive themes/ domains. "Indication" in MSC had the lowest ICC (.64;95%CI=.46-.77) with questionable reliability. F test comparing two variances was also lowest on indication $F(53, 212) = 2.76$, $p=0.0000$ rejecting the null hypothesis which assumed no difference between the three MSC domains as shown in table 4.1.

Table 4.1: ICC for MSC deductive themes (Source: Author, 2024)

MSC domains	Intraclass Correlation	95% Confidence interval		F Test with True Value 0			
		Lower Limit	Upper Limit	Value	df1	df2	P<0.001
Indication	.638	0.4594	0.7709	2.7637	53	212	0.0000
Ethics	.710	0.5582	0.8196	3.4535	52	156	0.0000
Implementation	.784	0.6870	0.8601	4.6223	53	530	0.0000

Excellent ICC >0.75 was observed for diagnostic accuracy, preferred capacity in diagnostic thinking and cost-effective implementation of AI in radiology with F values>4. Significant p value<0.0001 on all the domains rejected the null hypothesis which assumed no difference between the five RADAR rubric domains as shown in table 4.2.

Table 4.2: ICC for the RADAR rubric deductive themes (Source: Author, 2024)

RADAR rubric domains	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower Limit	Upper Limit	Value	df1	df2	P<0.0001
Technical properties?	.745	0.5982	0.8446	3.9267	52	104	0.0000
Diagnostic accuracy/ threshold in lesion detection?	.777	0.6501	0.8634	4.4900	53	106	0.0000
Preferred capacity in diagnostic thinking?	.794	0.6756	0.8734	4.8429	53	106	0.0000
Contribution of AI radiology to patient management?	.738	0.5882	0.8393	3.8149	53	106	0.0000
Rank cost effectiveness on implementation?	.780	0.6543	0.8651	4.5452	53	106	0.0000

4.6 HTA tool for AI in radiology

Statistical significance was referenced to median as a measure of central tendency since data was right skewed and reduced outlier effect was desired. Non parametric Wilcoxon signed rank test indicated statistical significance $p < 0.05$ against a median of 3 for all items as shown in table 4.3.

Table 4.3: Rapid assessment HTA tool for AI in radiology (Source: Author, 2024)

HTA core domains	HTA tool for AI in radiology	High n (%)	Moderate n %	Low n (%)	p<0.05
Health problem & current use of technology	Clinical benefit	47 (87)	3 (6)	4 (7)	0.0090
	Clinical risk management	46 (85)	5 (9)	3 (6)	0.0090
	Superiority to current practice	31 (57)	16(30)	7 (13)	0.0000
	Adaptability of the AI solution to the local institution	29 (54)	14(26)	11 (20)	0.0000
Description & technical characteristics	Frequency of AI detecting the lesion correctly	44 (81)	9 (17)	1 (2)	0.0020
	Ability of AI in detecting lesions correctly	39(72)	14(26)	1 (2)	0.0050
	Explainability of results from the AI software	45 (83)	8(15)	1 (2)	0.0000
	Multi dimensionality in lesion detection	39 (72)	9(17)	6 (11)	0.0000
	Ease of using the AI in the diagnostic workflow	41 (76)	12(22)	1 (2)	0.0000
	Willingness to use AI in actual radiology practice	32 (60)	10 (19)	12 (22)	0.0000
Safety	Recommendations from peer review publication	21 (39)	22 (41)	11 (20)	0.0000
	Ability to reduced diagnostic uncertainty	34 (63)	13 (24)	7 (13)	0.0000
Clinical effectiveness	Clinical validation of the AI software by radiologists	42 (78)	7 (13)	5 (9)	0.0010
	Ability to detect lesions accurately	45 (83)	8 (15)	1 (2)	0.0040
	Reliability of AI in detecting lesions accurately	43 (80)	4 (7)	7 (13)	0.0020
	Utility of the AI in clinical decision making	33 (61)	12 (22)	9 (17)	0.0000

Academic and research was added as a statistically significant new item as shown in table 4.4.

Table 4.4: Add on to complete full HTA tool for AI in radiology (Source: Author, 2024)

		High	Moderate	Low	
HTA core domains	**HTA items for AI in radiology**	n (%)	n (%)	n (%)	**p<0.05**
Cost & economic analysis	Affordability of AI implementation	33(61)	7 (13)	14 (26)	0.0000
	Cost effectiveness of AI implementation	33 (61)	17 (31)	4 (7)	0.0000
	Adaptability of the AI solution to the local institution	29 (54)	14 (26)	11 (20)	0.0000
	Installation Cost	33 (61)	15 (28)	6 (11)	0.0000
Ethical analysis	Doing good (Beneficence)	46 (85)	7 (13)	1 (2)	0.0070
	Doing no harm (Maleficence)	46 (85)	5 (9)	3 (6)	0.0080
	Patient freedom to choose (Autonomy)	26 (48)	19 (35)	9 (17)	0.0000
	Fairness (Justice)	33 (61)	4 (7)	17 (31)	0.0000
Organizational aspects	Ease of hardware integration	33(61)	16 (30)	5 (9)	0.0000
	Ease of software integration	39 (72)	12 (22)	3 (6)	0.0000
	Ease of using the AI in the diagnostic workflow	41 (76)	12 (22)	1 (2)	0.0000
	Willingness to use AI in actual radiology practice	32(59)	10 (19)	12 (22)	0.0000
	Use full ness of the AI results	30 (56)	21 (39)	3 (6)	0.0000
	Ability to integrate AI in the radiology diagnostic workflow	39 (72)	7 (13)	8 (15)	0.0000
Patient & social aspects	Actionable insights from the AI results	31 (57)	22 (41)	1 (2)	0.0000
	Influence on therapeutic interventions	30 (56)	20 (37)	4 (7)	0.0000
	Impact on patient outcomes	41 (76)	9 (17)	4 (7)	0.0010
Legal aspects	Regulatory approval of the AI software	33 (61)	15 (28)	6 (11)	0.0000
New aspect	Academic and research	32 (59)	16 (30)	6 (11)	0.0000

CHAPTER 5

DISCUSSION

5.1 Introduction to the chapter

This section summarizes key finding with relevant existing academic argument on AI in radiology globally.

5.2 Discussion

Radiology is a highly tech enabled and data rich medical field which fans AI innovation in healthcare. Most domain experts lack AI education which explains significant dissent on long term plans, knowledge gap on frequency of use of AI (Figure 4.1) and the number of participants in the radiology and radiography field (Figure 4.2). Mwaniki et al highlighted that almost 40% of radiologists are not willing to train AI/ML models in radiology which confirms the low participation among radiologist and radiographers (Mwaniki, 2023). Kawooya et al zones in on the meagre technological infrastructure for training and deployment of AI technologies (Kawooya, 2022). Despite these challenges, Hua et al posit that user acceptability and AI literacy among domain experts drives technological revolution which is value laden (Hua, 2024). This study provides a social technical assessment tool which promotes knowledge management as a driver of AI acceptability in radiology within Kenya and similar low resource set up.

Brady et al invite decision makers in value appropriation of AI in radiology through collaborative action research with software developers (Brady, 2024). Boverhof et in in the value assessment of AI in radiology proffers clinical assessment through cross-sectional, longitudinal, randomized clinical trials and insilico trials (Boverhof, 2024). Boverhof`s approach however muffles user centeredness in the social technical design (Brady, 2024; Hua, 2024). Rapid technological evolution is sustainably understood using the action research framework (Shani, 2019).Action research strategically favors co creation (Saunders, 2023). Multiple perspectives from stakeholders enrich standards, credibility and comprehensive inputs facilitated by multi criteria decision analysis (Martelli, 2016). Gongora Salazar et al in a scoping review of HTA in healthcare cites priority setting in decision making as a common application of MCDA (Gongora-Salazar, 2023) with statistical parameter validation (Ranganathan, 2024).

Ferizovik et al highlighted the lack of explicit tools in the HTA assessment of AI in radiology (Ferizovik, 2022). Farah et al affirms this when interrogating suitability of existing tools in radiology (Farah*, 2024). Deductive themes and items in this study were drawn from European and American standards (Kristensen, 2017; Boverhof, 2024; Brady, 2024) which limit contextual considerations. Africa and Asia lack explicit HTA tools (Kawooya, 2022; Mwaniki, 2023; Wee, 2024). The deductive themes and the individual items in the final tool were validated by strategic decision makers using dynamic tools that can be applied in various stages across AI lifecycle development; including design development and implementation of AI technologies in radiology (Farah, 2023; Boverhof, 2024; Brady, 2024).

Decision makers and domain experts prioritized all the deductive themes in the final tool; Comprehensive HTA tool for Radiology AI in Kenya (Appendix V)**.** RADAR rubric (Boverhof, 2024) and MSC considerations (Brady, 2024) are heterogenous which further informs Farah et al interrogation on the suitability of the existing HTA consideration (Farah*, 2024). The comprehensive HTA tool for radiology AI in Kenya proposes versatile valuation of AI in radiology within proposed global standards (Farah, 2023). This tool can further be deployed when translating the hypothetical case into an actual case, or as a generic value appraisal tool when deploying AI in radiology with relevant contextual modifications (Farah, 2023; Farah*, 2024). This explains a higher p value for line items as compared to the domain items (Figure 4.1-Figure 4.4)

Mwaniki highlights adoption inertia of AI in radiology within Kenya with lack of AI knowledge on related concepts (Mwaniki, 2023). Academics and research as a new aspect in the comprehensive HTA tool for radiology AI in Kenya underscores the relevance on knowledge management on AI in radiology which remains meager at best in Kenya and in Africa (Kawooya, 2022; Mwaniki, 2023). Bounded awareness and bounded rationality between software developers, healthcare managers and radiologists corrupt value delivery of AI in healthcare when they operate in silos (Brady, 2024; Hua, 2024). This research frames relevant domains that can inform the AI strategy in radiology addressing labor dynamics, technological sustainability and responsible AI.

Kawooya et al propose collaboration and AI technology in improving safety in radiology within Africa (Kawooya, 2022; Musa, 2023). Safety as a deductive theme within the comprehensive HTA tool for Radiology AI in Kenya draws line items from both the multi society consideration and the RADAR rubric (Appendix V, Figure 4.4). Positional statement from Asia fosters Kawooya`s proposition on adoption of safe AI as guided by bioethical principles (Wee, 2024). Comprehensive HTA tool for Radiology AI in Kenya, provisions for the four common bioethical principles in medical practice (Appendix V). This tool standardizes communication in favor of a collaborative framework responsive to Kawooya et al, Mwaniki et and Wee et al in domesticating and valuation of AI in radiology against global standards.

Europe and America conduct HTA through agencies and frameworks iterated in their own context. Leveraging on existing research reduces research waste however, where HTA approach is not explicit, novelty is warranted (Ferizovik, 2022; Farah*, 2024). AI in healthcare posits a new intricacy in HTA as transformative levers beyond software as medical devices (Alami, 2020). Value delivery is anchored on strong foundational principles such as HTA core model 3.0 in the holistic assessment of AI in radiology (Alami, 2020; Farah, 2023) The Comprehensive HTA tool for Radiology AI in Kenya proposes utility value points in low resource set up.

Value appropriation of the utility value points was delegated to strategic stakeholders and articulated using MCDA. MCDA provides analytical versatility on complexity, skill, technology, modelling and iterations (AFCT, 2024). Boverhof et al proposes MCDA in the alignment of local requirements using local stakeholders (Boverhof, 2024). Systemic literature review in 2020 on MCDA dominance in healthcare complements our study on its application in priority setting during decision making (Gongora-Salazar, 2023). It confirms high priority on user/ patient facing attributes with low priority on cost and peer recommendation attributes. Potential bounded awareness on AI related concepts confirmed by Mwaniki et al explains this divergence (Mwaniki, 2023). Moreover, divergence on scoring and weighting in the systematic literature review was predominantly through modelling and linear regression techniques as opposed to expert opinions and Likert scales in this study. Modelling and linear regression techniques were not warranted due to a small decision-making apex; 54 respondents.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATION

6.1: Introduction to the chapter

This chapter draws conclusions from key findings in the study and provides tiered recommendation on the way forward.

6.2 Conclusions and recommendation

Generically, AI in radiology is a rapidly developing value laden technology supporting patient safety, operational efficiency and professional innovation. This warrants user acceptability by decision makers through articulation of value proposition on multiple attributes against local and global standards. This study recommends a decision-making tool in a low resource set up for decision makers who influence deployment of AI in radiology in health care management/clinical practice, digital health, policy/ regulation, academics/ research and radiology medical practitioners.

Technically, attributes of the tool support AI literacy, shared communication and credibility in rationale and group decision making. This sets the base for training institutions and regulatory bodies on health technology assessment that build into the AI strategy in radiology and healthcare at large. Healthcare system is highly interconnected therefore inter-disciplinary collaboration enriches AI literacy widening the window of opportunity and voice aggregates informing sound policy recommendations with evidence-based iterations, monitoring and evaluation.

Globally, AI favors business re-engineering which confers competitive advantage in radiology as a discipline as well as Kenya as a medical tourist destination. Coordinated development and deployment of AI in radiology nested within relevant policies and strategies hosts digital commodities which can be exported regionally and developed locally beyond the traditional competencies and technologies in radiology. This favorable innovative milieu within and beyond healthcare attracts resources for learning, growth and development in the country and the healthcare industry.

References

Abbas, R. a. (2023). Socio-Technical Theory: A review. In S. Papagiannidis, *Theory Hub Book* (pp. 1-16). NewCastle: TheoryHub Book.

Abbasian, M. K. (2024). Foundation metrics for evaluating effectiveness of healthcare conversations powered by generative AI . *Nature Portfolio Journal- Digital Medicine*, 1-14.

AFCT, A. F.-U. (2024, Oct 31). *An introductory guide to multicriteria decision analysis*. Retrieved from Government Analysis Function: https://analysisfunction.civilservice.gov.uk/policy-store/an-introductory-guide-to-mcda/

Ahsan, M. a. (2022). Industry 4.0 in Healthcare: A systematic review. *International Journal of Information Management Data Insights.*, 1-14.

Alami, H. L. (2020). Artificial Intelligence and Health Technology Assessment: Anticipating a New Level of Complexity. *Journal of medical Internet Research*.

Alowais, A. A. (2023). Revolutionizing healthcare: the role of artificial intelligence in clinical practice. *BMC Medical Education*, 1-15.

Anyoha, R. (2017). The history of Artificial Intelligence: Can machines think? *Harvard University- Special Edition of Artificial Intelligence.*

Bastedo, M. (2004). Open Systems Theory. *The SAGE Encyclopedia of Educational Leadership and Administration*, 1-2.

Boverhof, B.-J. R. (2024). Radiology AI Deployment and Assessment Rubric (RADAR) to bring value-based AI into radiology practice. *European Society of Radiology Insights into Imaging*, 1-10.

Brady, A. A. (2024). Developing, Purchasing, Implementing and Monitoring AI tools in radiology. *Radiology: Artificial Intelligence*, 1-16.

Castonguay, A. W. (2024). AI maturity in health care: An overview of 10 OECD countries. *Health Policy*.

Cheikh, A. G. (2022). How artificial intelligence improves radiological interpretation in suspected pulmonary embolism. *IMAGING INFORMATICS AND ARTIFICIAL INTELLIGENCE - European Radiology.*, 1-12.

Dawadi, S. S. (2021). Mixed-Methods Research: A Discussion on its Types, Challenges, and Critisms. *Journal of Practical Studies in Education.*, 25 - 36.

Dwivedi, Y. S. (2023). Evolution of artificial intelligence research in Technological Forecasting and Social Change: Research topics, trends, and future directions. *Technological Forecasting & Social Change.*, 1-17.

European Society of radiology. (2021). Value-based radiology: what is the ESR doing and What should we do in the future. *Insights into imaging.*, 1-7.

Farah, L. B. (2024). Suitability of the Current Health Technology Assessment of Innovative Artificial Intelligence-Based Medical Devices: Scoping Literature Review. *Journal of Medical Research*, 1-18Farah, L., Borgete I., Martelli A and Vallee N.

Farah, L. M. (2023). Mayo Clinical Proceedings: Digital Health. *Assessment of Performance, Interpretability,and Explainability in Artificial Intelligence Based Health Technologies: What Healthcare Stakeholders Need to know*, 120-138.

Faric, N. H. (2024). Early experiences of integrating an artificial intelligence-based diagnostic decision support system into radiology settings: a qualitative study. *Journal of American Medical Informatics Association*, 24-34.

Feng, Q. (2022). Analysis of Technological Determinism and Social. *8th International Conference on Humanities and Social Science Research* (pp. 1-4). Boston: Atlantis Press.

Ferizovik, N. a. (2022). RECOMMENDATIONS ON THE USE OF ARTIFICIAL AND MACHINE LEARNING IN SYSTEMATIC LITERATURE REVIEWS SUBMITTED AS PART OF THE EVIDENCE PACKAGE IN HEALTH TECHNOLOGY. *Value Health*, 1.

Fernandesa, C. C. (2022). The evolution of IS/IT in health care in last decades: Mobile system and Perversive computing for personalized medicine (M4Medicine). *International Workshop on mobile4medicine* (pp. 707–713). Niagra falls, Ontario, Canada: Elsevier B.V.

Fryback, D. a. (1991). The Efficacy of Diagnostic Imaging. *Society of Medical Decision Making*.

GoK, G. o. (2012). Laws of Kenya. *Pharmacy and Poisons Act Chapter 244,* 1-114.

GoK, R. o. (2019). Laws of Kenya . *The Digital Act No 24 of 2019*, 1-37.

GoK, R. o. (2023). Laws of Kenya. *The Digital Health Act No. 15 of 2023,* 1-29.

Gongora-Salazar, P. R.-A. (2023). The Use of Multicriteria Decision Analysis to Support Decision Making in Healthcare: An Updated Systematic Literature Review. *Value Health,* 780-790.

Howell, M. C. (2024). Three Epochs of Artificial Intelligence in Health Care. *Journal of American Medical Association*, 242-244.

Hua, D. P. (2024). Understanding the factors influencing acceptability of AI in medical imaging domains among healthcare professionals: A scoping review. *Artificial intelligence in medicine*, 1-14.

Huebner, C. a. (2022). Strategic Management in Healthcare: A Call for Long-Term and Systems-thinking in an uncertain system. *International Journal of environmental research and public health*, 1-17.

Kahn, R. a. (2022). Pulmonary Embolism. *New England Journal of Medicine- Clinical Practice.*, 1-13.

Kahraman, A. F. (2023). High Performance Embolism Detection in Real-World CT Pulmonary Angiography Examinations Using Deep Learning. *MedRXiv*, 1-32.

Kaplan, S. U. (2024). A unified and practical user-centric framework for explainable artificial intelligence. *Knowledge based system*, 1-14.

Kawooya, M. K. (2022). An Africa point of view on quality and safety. *Insights into Imaging.*, 1-10.

KEBS, K. B. (2024). Information technology — Artificial Intelligence — Code of Practice for AI Applications. *Kenya Standard*, 1-43.

Kristensen, F. L. (2017). The HTA Core Model®—10 Years of Developing an International Framework to Share Multidimensional Value Assessment. *Value Health*, 244-250.

Line, F. M. (2023). Mayo Clinical Proceedings: Digital Health. *Assessment of Performance, Interpretability,and Explainability in Artificial Intelligence Based Health Technologies: What Healthcare Stakeholders Need to know*, 120-138.

Lugerta, A. V. (2018). Dynamization of Value Stream Management by technical and managerial. *51st CIRP Conference on Manufacturing Systems.*, 701 - 706.

Martelli, A. H. (2016). Combining multi-criteria decision analysis and mini-health technology assessment: A funding decision-support tool for medical devices in a university hospital setting. *Journal of bioinformatics*, 201 -208.

Masic, I. (2014). Five Periods in Development of Medical Informatics. *Acta Informatica Medica-Journl of Medical Sciences of Bosnia and Herzegovina.*, 44 - 48.

Masic, I. (2022). Medical Decision Making - an Overview. *Acta Informatica Medica*, 230-235.

Muehlbauer, K. W. (2022). Data driven logistics-oriented value stream mapping 4.0: A guideline for practitioners. *International Federation of Automatic Control. Papers On Line.*, 364–369.

Musa, S. H. (2023). Paucity of Health Data in Africa: An Obstacle to Digital Health Implementation and Evidence-Based Practice. *Public Health Review.*, 1-5.

Mwaniki, K. O. (2023). The Role of Artificial Intelligence in Diagnostic : Knowledge, Attitude, and Practice of Radiologists and Radiology Residents in Kenya. *Europe PMC.*, 1-22.

Mwanza, J. T. (2023). Impact of industry 4.0 on healthcare systems of low- and middle- income countries- a systemic review. *Health and Technology.*, 35-52.

Nabrawi, E. a. (2023). Imaging in Healthcare: A Glance at the Present and a Glimpse Into the Future. *Cureus*, 1-6.

Najjar, R. (2023). Redefining Radiology: A Review of Artificial Intelligence Integration in Medical Imaging. *MDPI diagnostics.*, 1-25.

Pierre, K. H. (2023). Applications of Artificial Intelligence in the Radiology Roundtrip: Process Streamlining, Workflow Optimization, and Beyond. *Seminars of Roentgenology.*, 158 - 169.

Rahimi, S. a. (2024). Saturation in qualitative research: An evolutionary concept analysis. *International Journal of nursing studies advances*, 1-11.

Ranganathan, P. C. (2024). Designing and validating a research questionnaire - Part 2. *Perspectives in Clinical Research*, 42-45.

Ropohl, G. (1999). Philosophy of socio-technical systems. *Teche: Research in philosophy and technology*, 186-194.

Saunders, M. L. (2023). *Research methods for business students 9th Ed.* Harlow: Pearson Education Limited.

Shani, A. C. (2019). Action research in business and management: A reflective review. *Action Research-SAGE journals*, 518-541.

SORK. (2024, Oct 15). *Medical Radiographers*. Retrieved from Society of Radiography in Kenya: https://sork.or.ke/medical-radiographers/

Ul Islam, N. Z. (2024). Seeking an optimal approach for Computer-aided Diagnosis of Pulmonary Embolism. *Medical Imaging Analysis.*, 1-3.

Wan, T. a. (2020). Understanding the Difference Between Healthcare Informatics and Healthcare Data Analytics in the Present State of Health Care Management. *Health Services Research and Managerial Epidemiology.*, 1-3.

Wee, N. G. (2024). Position Statements of the Emerging Trends Committee of the Asian Oceanian Society of Radiology on the Adoption and Implementation of Artificial Intelligence for Radiology. *Korean Journal of Radiology*, 603-612.

White, M. (2023). Sample size in quantitative instrument-based studies published in Scopus up to 2022: An artificial intelligence aided systematic review. *Acta Psychologica*, 1- 8.

WHO. (2010). Key components of a well functioning health system. *World Health Organization.*, 1-2.

WHO, W. H. (2023). *Evidence and lessons on health technology assessment and health benefit packages in the WHO African Region.* Brazzaville: World Health Organization.

Yardanova, M. (2024). The Applications of Artificial Intelligence in Radiology: Opportunities and Challenges. *European Journal of Medical and Health Science*, 11-14.

APPENDICES

Appendix 1: Introduction Letter

/2024

Strathmore Business School

Nairobi

Dear Respondent,

Re: Introduction letter seeking informed consent.

I am Miriam Miima a graduate student of Master of Business Administration- Healthcare Management degree at the Strathmore University Business School. I am carrying out a research study in partial fulfillment of my degree award of the degree and enhancing my knowledge on AI in healthcare. The study is titled the “**Health technology assessment of artificial intelligence in radiology”**

I wish to request for your participation with guaranteed confidentiality of the data collected. The outcome of this study will be local framework for health technology assessment of an artificial intelligence enabled pulmonary embolism detection software. The findings of the study will be availed to you at your request. Any assistance offered in the collection of data will be deeply appreciated.

Yours faithfully,

Miriam Miima

Investigator

Appendix II: Participant's Information and Consent Form

My name is Miriam Miima a student of Healthcare Management at the Strathmore University. I am carrying out a research study titled **Health technology assessment of artificial intelligence in radiology**. The study has been approved by the institutional scientific ethical review committee. Ref no. SU-ISERC2327/24. and NACOSTI license no: NACOSTI/P/24/38065

The objective of this survey is to improve construct and content validity an assessment tool which will inform an appraisal framework of AI in radiology. In this study think of an AI enabled software that can detect pulmonary embolism on CT scan images as an example.

Eligible participants are clinical/ non clinical medical doctors and radiographers familiar with the radiology diagnostic workflow. The questionnaire can be filled in approximately 5-10 minutes.

The findings of the study will be availed to you on request. Any assistance offered in the collection of data will be highly appreciated.

Participant's Signature: …………………………… Date …………………………

Do you agree to participate in the study

- **Yes**
- **No**

Do you wish to receive the findings of this study?

If YES, please indicate your email address below OR

Kindly reach out to me on: Email: miriam.miima@strathmore.edu OR

Phone number: 0721917972

THANK YOU

Appendix III: Radiology multi society practical considerations .

IMPLEMENTATION PRIORITY LEVEL			
INDICATION	High	Moderate	Low
Regulatory			
Clinical benefit			
Clinical risk management			
Competitive advantage			
Cost effectiveness			
Academic and research			
ETHICS			
Doing good (Beneficence)			
Doing no harm (Non maleficence)			
Patient freedom to choose (Autonomy)			
Fairness (Justice)			
MODEL CONSIDERATIONS			
Superiority to current practice			
Explainability			
Multi dimensionality			
Hardware integration			
Software integration			
Installation cost			
Maintenance cost			
MODEL CONSIDERATIONS	High	Moderate	Low
Peer review publication			
Regulatory approval			
Model accuracy			
Clinical validation			
Monitoring/ update schedule			
HUMAN – AI CONSIDERATIONS			
Self-efficacy			
Ease of use			
Willing ness to use in daily practice			
Trust in the model			
Accuracy of the model			
Validation of the model			
LONG TERM STABILITY			
Strategic			
What`s the problem, risk and benefit?			
Regulatory compliance			
Legal and ethical			
Performance			
Efficacy, monitoring, fairness			

Workflow integration			
Ease of use			
Technical			
Infrastructure and skill			
Economic costs			
Can return on investment be monitored			

Appendix IV: RADAR rubric

IMPLEMENTATION PRIORITY LEVEL			
Technical properties?	**High**	**Mod**	**Low**
Frequency of AI detecting the lesion correctly			
Ability of AI in detecting lesions correctly			
Explainability of results from the AI software			
Diagnostic accuracy/ threshold in lesion detection?			
Ability to detect lesions accurately			
Reliability of AI in detecting lesions accurately			
Utility of the AI in clinical decision making			
Preferred capacity in diagnostic thinking?			
Use full ness of the AI results			
Ability to integrate AI in the radiology diagnostic workflow			
Ability to reduced diagnostic uncertainty			
Contribution of AI radiology to patient management?			
Actionable insights from the AI results			
Influence on therapeutic interventions			
Impact on patient outcomes			
Rank cost effectiveness on implementation?			
Affordability of AI implementation			
Cost effectiveness of AI implementation			
Adaptability of the AI solution to the local institution			

Appendix V: Comprehensive HTA tool for Radiology AI in Kenya

HTA core domains	HTA tool for AI in radiology	High	Moderate	Low
Health problem & current use of technology	Clinical benefit			
	Clinical risk management			
	Superiority to current practice			
	Adaptability of the AI to the local institution			
Description & technical characteristics	Frequency of AI detecting the lesion correctly			
	Ability of AI in detecting lesions correctly			
	Explainability of results from the AI software			
	Multi dimensionality in lesion detection			
	Ease of using the AI in the diagnostic workflow			
	Willingness to use AI in radiology practice			
Safety	Recommendations from peer review publication			
	Ability to reduced diagnostic uncertainty			
Clinical effectiveness	Clinical validation of the AI software by radiologists			
	Ability to detect lesions accurately			
	Reliability of AI in detecting lesions accurately			
	Utility of the AI in clinical decision making			
Cost & economic analysis	Affordability of AI implementation			
	Cost effectiveness of AI implementation			
	Adaptability of the AI solution to the local institution			
	Installation Cost			
Ethical analysis	Doing good (Beneficence)			
	Doing no harm (Maleficence)			
	Patient freedom to choose (Autonomy)			
	Fairness (Justice)			
Organizational aspects	Ease of hardware integration			
	Ease of software integration			
	Ease of using the AI in the diagnostic workflow			
	Use full ness of the AI results			
	Integration of AI in the radiology workflow			
Patient & social aspects	Actionable insights from the AI results			
	Influence on therapeutic interventions			
	Impact on patient outcomes			
Legal aspects	Regulatory approval of the AI software			
New aspects	Academic and research			

Appendix VI: SU IREC ethical approval letter

Strathmore
UNIVERSITY

4th July 2024

Dr Miima Miriam,
miriam.miima@strathmore.edu

Dear Dr Miima,

RE: Health Technology Assessment of Artificial Intelligence in Radiology: Pulmonary Embolism Detection Software

This is to inform you that SU-ISERC has reviewed and **approved** your above **SU-masters** proposal. Your application reference number is **SU-ISERC2327/24.** The approval period is from **4th July 2024 to 3rd July 2025.**

This approval is subject to compliance with the following requirements:

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-ISERC.
iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to SU-ISERC within 72 hours of notification.
iv. Any changes anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-ISERC within 72 hours.
v. Clearance for the export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to the expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days of completion of the study to SU-ISERC.

Before commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology, and Innovation (NACOSTI) https://research-portal.nacosti.go.ke/ and obtain other clearances needed.

Yours sincerely,

Mr Ambrose Rachier,
Chairperson; SU-ISERC

Ole Sangale Rd, Madaraka Estate. PO Box 59857-00200, Nairobi, Kenya. Tel +254 (0)703 034000
Email admissions@strathmore.edu www.strathmore.edu

Appendix VII: NACOSTI ethical approval letter

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **387872**

Date of Issue: **24/July/2024**

RESEARCH LICENSE

This is to Certify that Dr.. Miriam Miima of Strathmore University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: HEALTH TECHNOLOGY ASSESSMENT OF ARTIFICIAL INTELLIGENCE IN RADIOLOGY: PULMONARY EMBOLISM DETECTION SOFTWARE for the period ending : 24/July/2025.

License No: **NACOSTI/P/24/38065**

387872

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions