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Consultancy Frameworks for AI-Driven Medical Imaging: Advancing Early Diagnosis in Healthcare Systems

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ABSTRACT

While the integration of AI (artificial intelligence), its application in medical imaging is rapidly changing the world of diagnostics, some health systems have yet to develop specific design guides to offer guidance for how we make AI usage in medical imaging safe and ethically sound, whilst in a way that could scale to a wider context with good security. We now present a consultancy system for AI-driven medical imaging for early diagnosis in Saudi Arabia. Based on international standards like SPIRIT-AI, CONSORT-AI, CLAIM, DECIDE-AI and the WHO Ethics and Governance of AI for Health, the framework covers essential obligations for responsible AI use.

An expert perspective approach was used to gather the expertise in the field by utilizing qualitative design based on healthcare professionals, radiology practitioners, biomedical engineering and digital health specialists deployed in Saudi Arabia. Some of the more specific domains identified in this analysis relate to readiness assessment, workflow integration, interoperability, data governance, cybersecurity, explainable AI (XAI), federated learning, regulatory alignment with FDA, AI Act, and continuous metrics. The results indicate that the successful introduction of AI in medical imaging should be achieved within an organisational consultancy model, with ethical restrictions and technical validation, adaptation of clinical workflow and stakeholder participation. The framework developed provides applicable recommendations for healthcare institutions working to incorporate AI-assisted imaging tools to optimize early diagnosis, enhance efficiency in radiology, as well as to promote global AI governance best practices. We add to the growing digital health literature by providing a contextualized evidence-informed model aimed at supporting strategizing judgments and fast-tracking the move to AI enabled diagnostic platforms in Saudi healthcare systems.

Keywords: Medical imaging AI-enabled; consultancy frameworks; early diagnosis tools; radiology workflow integration; digital health transformation; explainable AI (XAI); federated learning; AI governance; SPIRIT-AI; CONSORT-AI; CLAIM checklist; DECIDE-AI; FDA AI-enabled devices; EU AI Act; WHO AI ethics; interoperability; data governance; biomedical engineering; Saudi healthcare settings.

INTRODUCTION

Background

Artificial Intelligence (AI) has played a key role in contemporary medical imaging, and machine learning has begun to play a key role in image detection, triage, reporting and quality control in radiology. Findings from large-scale trials suggest that AI systems can obtain clinically valuable performance if designed in strong data sets and transparent validation (McKinney et al., 2020; Rajpurkar et al., 2022). Technical correctness does not by itself bring clinical benefit. The practical use of AI in clinical practice will rely on how readily technology can be integrated within radiology workflows, interoperability with legacy PACS/RIS systems, clinician confidence, and the organization's systems for ongoing monitoring and governance (Tejani, Cook, et al., 2024; Willemink et al., 2020). Many health care systems (including those in the process of digital transformation) are focused on AI-mediated imaging in order to facilitate early diagnosis, expedited reporting of diagnosis and standardised care flow. National strategies that underscore quality, efficiency, prevention, and digital health innovation enable the promotion of good prospects for AI adoption (Alasiri & Mohammed, 2022). Yet adopting

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technology can't be achieved on its own. Hospitals have to integrate AI deployment into clinical governance, workflow design, data management, cybersecurity and ethical principles as proposed by international organizations like the World Health Organization (2021).

Research Problem

Despite its application in early diagnosis and radiology, the adoption of AI in healthcare generally is patchy. Adoption is often spearheaded by vendor-specific interventions, isolated pilot projects or department-level experimentation. The key issue that this research tackles is that existing consultancy frameworks, which have been validated in general, do not provide the necessary guidance for healthcare institutions to consider readiness assessment, technology choice, workflow redesign, governance alignment, validation, deployment and constant monitoring. Without such organization, AI adoption can be extremely heterogeneous among facilities, leading to disparate results and the delayed arrival of diagnostic tools.

Research Gap

The existing literature offers reporting guidelines, governance guidance and technical standards for AI applications in healthcare like CONSORT-AI, SPIRIT-AI, CLAIM, DECIDE-AI, and other evaluation guidance frameworks (Cruz Rivera et al., 2020; Liu et al., 2020; Mongan et al., 2020; Vasey et al., 2022). Yet these resources provide no consultancy-based model responsive to the operational realities of healthcare imaging environments such as radiology workflows, PACS/RIS integration, early diagnosis and national digital health strategies. This study seeks to fill this gap through developing and validating a contextualized consultancy model for AI-driven medical imaging provision in healthcare systems on the basis of expert opinions from professionals working in Saudi Arabia.

Objectives of the Study

Broadly, this study aims to create a consultancy framework for AI's adoption in medical imaging implementations within healthcare systems in support of their successful execution and validation. In particular, the study specifically seeks to:

Identify major barriers and enablers of adoption of AI in medical imaging environments.

Develop a consulting framework covering clinical, technical, organizational and governance aspects.

Evaluate the framework by experienced professionals on clarity, relevance, completeness, feasibility, and quality.

Iterate the framework after qualitative expert discussion and quantitative validation analyses.

Research Questions

The study thus is guided by the following questions:

1. What are the barriers and drivers to AI adoption in the context of medical imaging environment?
2. What core components should AI-driven early diagnosis be built on in terms of consultancy?
3. How do experts grade a proposed framework for clarity, relevance, completeness, practicality and overall quality?
4. How can it be aligned with current AI governance standards and national digital health priorities?

Significance of the Study

This study has implications for clinical, technical, organizational, and governance audiences of health systems. Clinically, it offers radiologists and imaging teams a stepwise pathway to implement AI without derailing clinical

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practice. Technically, it notes interoperability, data preparation, security and PACS/RIS integration as crucial for AI adoption (Tejani, Cook, et al., 2024; Willemink et al., 2020). Strategically, it connects AI adoption to more extensive priorities of health transformation. At the governance level, it materializes principles of transparency, accountability, human oversight, safety, privacy, and continuous reassessment in actionable steps (Amann et al., 2020; European Parliament and Council of the European Union, 2024; World Health Organization, 2021).

LITERATURE REVIEW

Medical Imaging, early diagnosis in AI systems.

AI-based imaging systems have been widely explored in a variety of aspects such as cancer screening, diagnostic support, triage, segmentation, and clinical decision support. For AI-based systems, this has led researchers to develop innovative methods for early diagnosis, to detect disease in the initial stages of illness as well as for early diagnosis. Large-scale evaluations such as that from McKinney et al., for example, the international assessment of an AI system for breast cancer screening (2020), have indicated that AI is capable of clinically meaningful performance in particular image scanning tasks. General summaries of AI in health and medicine have shown that clinical benefit is contingent not only on the accuracy of algorithms but also on safe design of programs, a representative model and practice that uses representative datasets which could be evaluated in the future, and responsible deployment (Rajpurkar et al.). Not only do these results indicate AI's prospects for enhancing early diagnosis, but they make clear that technical performance is not enough for successful clinical integration on its own. This paper underscores the fact that data preparation is key to a successful integration of AI technology in medical imaging. Willemink et al. (2020) emphasize curated, annotated, standardized and well-governed imaging datasets for machine learning results. Roberts et al. (2021) also warn that poor data sources, inconsistent validation of results, or inadequate reporting can compromise imaging AI research reliability. This knowledge can validate the strategic incorporation of data pre-processing, validation, and continuous monitoring in the consultancy model presented in this study.

Readiness, acceptance, and human aspects.

The adoption of AI in healthcare is a sociotechnical process and necessitates harmonizing people, process, systems and institutional readiness. Human-centric assessments suggest that even if AI tools perform well, there may still be adoption barriers, such as lack of fit with clinical experience, unmet user requirements, or operational limitations (Abràmoff et al., 2020; Chen et al., 2021). In the Saudi context, national digital health programmes following Vision 2030 have stimulated interest in AI-enabled imaging but its adoption remains an issue of workforce readiness, organisational maturity, governance frameworks and clinician confidence (Alasiri & Mohammed, 2022; Alsaedi et al., 2024). Trust in AI is also strongly attached to explainability and accountability. Amann et al. (2020) maintain that explainability in healthcare AI must be understood from clinical, ethical, technical, and social vantage points. According to the study conducted by Tjoa and Guan (2021) and by van der Velden et al. (2022) demonstrates that explainable AI (XAI) can facilitate transparency with respect to medical image analysis, while methods of explanation must be interpreted with care. These results underscore the importance of integrating governance, clinical acceptability, and human centered design into AI development frameworks.

Workflow integration, interoperability and technical governance.

A successful deployment of AI in radiology necessitates an integration of the technology with current imaging workflow such as image acquisition, worklist management, PACS/RIS routing, reporting, communication of results, and quality assurance. Tejani, Cook, et al. (2024) highlight that interoperability through standards-based frameworks is an absolute must for scaling AI in radiology. The issue is not simply whether an AI model can generate an output, but whether that output reaches the right person at the right time in a hospital’s clinical workflow. Commercial AI products, on the other hand, differ widely in the extent of scientific evidence to support clinical use. van Leeuwen et al. (2021) discovered that a number of radiology AI products differ greatly in their supporting evidence quality and extent, and as a result structured evidence review is crucial prior to purchase or installation. Privacy preserving, federated learning solutions are becoming more relevant, notably

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when healthcare facilities cannot easily collect sensitive imaging information. Rieke et al. (2020), Kaissis et al. (2020), and Sharma and Guleria (2023, respectively) identify federated learning as one exciting avenue for multi-institutional AI development—but with challenges of security, generalizability, governance, and technical complexity.

Governance, Ethics, and Regulatory expectations.

In response to this, responsible AI implementation necessitates the implementation of governance structures covering safety, accountability, transparency, bias, privacy, as well as post-deployment monitoring, especially in a way that makes it possible for individuals to recognize and respond to the risks as they arise. International guidelines from the World Health Organization (2021) and the European Union Artificial Intelligence Act (European Parliament and Council of the European Union, 2024) highlight principles including human oversight, fairness, privacy, security and accountability. Reddy et al. (2020) and Morley et al. (2020), governance needs processes to operationalize, through policies, rules regarding roles, risk mitigation mechanisms, and ethics reviews, rather than simply at the level of the broader principles. Regulations related to AI-enabled medical devices are ever-evolving. Benjamens et al. (2020) reported the rapid proliferation of AI/ML–based medical devices that show regulatory authorization, and the U.S. Food and Drug Administration (n.d.) has a public list of AI–enabled medical devices it publishes. These developments show healthcare systems should examine vendor claims, regulatory standing, validation evidence, and clinical risk carefully before introducing AI solutions. There are numerous reporting and evaluation guidelines regarding the development and assessment of AI for medical imaging. The Checklist for Artificial Intelligence in Medical Imaging (CLAIM) offers a structured and uniform reporting regime for authors and reviewers (Mongan et al., 2020), with the 2024 update reflecting evolving expectations for AI reporting (Tejani, Klontzas et al., 2024). CONSORT–AI and SPIRIT–AI advance clinical trial reporting and protocol standards for AI-based interventions (Cruz Rivera et al., 2020; Liu et al., 2020). DECIDE–AI provides a foundation framework for early-stage clinical evaluation of AI-driven decision-support systems (Vasey et al., 2022). Vollmer et al. (2020) also propose critical questions in relation to transparency, reproducibility, ethics, and effectiveness that must be solved in medical machine learning research. These standards also influence the consultancy framework that focuses on validation, transparency, stakeholder involvement and responsible reporting. 2.6 Synthesis. The literature indicates that there is great promise in AI medical imaging based system in advancing early diagnosis, but successful AI in medical imaging implementation should be approached with a degree of caution. Safe and successful adoption demands organisational preparedness, integration of workflow, compliance, explainability, ethical governance, clinical evaluation and ongoing assessment. Despite the fact that existing guidances cover much of these areas, they do not involve a consultancy-based solution customized to the operational aspects of healthcare imaging settings. This study aims to address this void by developing a systematic consulting framework that combines strategic alignment, clinical workflow, technical infrastructure, and governance for one unified AI-based medical imaging adoption model, for medical imaging.

METHODS

Research Design.

This study also followed a sequential mixed-methods design in developing and validating a consultancy framework that helped AI-driven medical imaging implementation in healthcare systems. The qualitative phase sought out expert perspectives on barriers to adoption, workflow needs, technical integration, and governance considerations. The quantitative element involved a structured validation questionnaire to evaluate proposed structure. The nature of the design proposed was justified by the study's need for contextual and measurable expert examination.

Framework Design Process.

The framework was formulated in six phases: problem analysis, framework design, prototype construction, expert testing, data analysis, and refinement. These were consistent with the existing literature on AI reporting, governance and clinical assessment (Liu et al., 2020; Mongan et al., 2020; Vasey et al., 2022).

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- Stage 1: Determine adoption barriers or implementation needs in AI-assisted imaging.
- Stage 2: Develop a model based on the integrated structure with clinical and technical, organisational, as well as governance elements.
- Stage 3: Development of a validation instrument and framework prototype.
- Stage 4: Carry out expert review: Interviews and Survey evaluation.
- Stage 5: Qualitative and quantitative findings.
- Stage 6: Consultation structure and experts feedback to perfect the consultancy architecture.

Participants and Sampling.

It was a purposive sampling study to get experts that are experts on radiology, biomed engineering and PACS/RIS administration; digital health, AI governance, AI imaging deployment. The evaluators and respondents included healthcare practitioners who currently work in hospitals and medical establishments in Saudi Arabia. We did not collect any institutional data from the Ministry of Health, nor did we need an authorization because we focused primarily on expert assessment rather than organizational record. The number of experts was 17 in total. This sample size provided an appropriate sample size for exploratory framework validation, as the goal is expert-informed assessment rather than statistical generalization.

Table 1.

Participant Group	Role in AI-Driven Medical Imaging	Number
Radiologists	Assess clinical usefulness, diagnostic workflow, and early diagnosis value	4
Radiology department heads	Assess operational fit, workflow redesign, and departmental feasibility	2
Biomedical engineers	Assess equipment, safety, and technical feasibility	3
PACS/RIS administrators	Assess data flow, system integration, interoperability, and reporting linkage	2
Digital health & AI governance officers	Assess policy alignment, governance, cybersecurity, and compliance	4
AI imaging vendor specialists	Assess technical deployment requirements and product behavior	2
Total		**17**

Note. Participant groups reflect the 17 expert validators recruited through purposive sampling.

Criteria for Inclusion and Exclusion

Participants were required to have at least 3 years of experience in the areas of radiology, biomedical engineering, digital health, AI governance, PACS/RIS systems, or medical imaging technology as well as an ability to critique the suggested method of analysis. Exclusions were irrelevant experience, no participation in AI decision-making or implementation, and unwillingness to complete the interview or questionnaire.

Research Instruments

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Two instruments were used:

1.Semi-structured interview guide – examined barriers, issues in functioning/workflows, technical integration, governance, consultancy,

2. Anticipated framework elements item Likert-scale questionnaire – assessed the clarity of framework, relevance, completeness, practicality, and overall evaluation.

14-Responses ranged from 1 (strongly disagree) to 5 (strongly agree).

Table 2. Surveys for Framework Validation

Construct	Code	Survey Item
Clarity	C1	The framework is clearly structured.
	C2	The components are easy to understand.
	C3	The workflow is logical and coherent.
Relevance	R1	The framework addresses real challenges in AI imaging.
	R2	The framework is relevant to radiology workflows in healthcare settings. (MOH reference removed)
	R3	The framework aligns with clinical and technical needs.
Completeness	CP1	The framework includes the necessary implementation components.
	CP2	The consultancy processes are comprehensive.
	CP3	Governance and policy considerations are adequately covered.
Practicality	P1	The framework can be realistically implemented.
	P2	The framework supports early diagnosis using AI imaging.
	P3	The framework improves decision-making for AI adoption.
Overall Evaluation	O1	I am satisfied with the framework.
	O2	I would recommend the framework for adoption in healthcare systems.

Data Collection Procedure

Data was collected in two phases. In the qualitative phase, researchers examined the original framework and conducted semi-structured interviews to probe about barriers to adoption, workflow fit, technical integration, governance, and consultancy needs. During the quantitative phase, the same specialists who were employed as the initial team members filled out the 14-item validation questionnaire. This progressive approach allowed qualitative views to inform the framework and quantitative results to assess its perceived quality and reliability.

Data Analysis

Qualitative data were analyzed with thematic analysis: familiarization, initial coding, theme development, review, and interpretation. Topics included alignment with clinical workflow, technical integration and interoperability, governance and regulatory compliance, readiness of the organization, and consultancy. Descriptive statistics and reliability testing were used for quantitative data analysis. Means, standard deviations, and score ranges were calculated for each item. Composite scores were computed by averaging items under each

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construct. Cronbach's alpha was used to assess internal consistency. Because the sample was purposively chosen, findings were reported descriptively rather than statistically; the findings were reframed for use not as population-level generalizations.

Ethical Considerations

The study did not include patient records, clinical images, or identifiable patient names. Participation was voluntary and informed consent was obtained prior to data collection. Responses from interviewees were anonymized, and study data were securely stored. Finally, any ethics approval number given by the institution was included in the journal submission.

RESULTS

Overview of Findings

Results connect qualitative themes as well as quantitative validation scores. In general, the consultation framework was deemed clear, relevant, comprehensive, and practical as a reference plan for formal AI-based medical imaging adoption in health systems. These results all signal a strong expert agreement on the benefits of the framework in terms of the early diagnosis and responsible adoption of AI in healthcare systems.

Qualitative Themes

We made a thematic analysis to identify 5 central themes and subthemes. The themes are presented in Table 3 along with expert interview insights and findings and their relevance to the consultancy framework. These insights reveal how expert views were translated into applicable actionable guidelines for AI-led imaging adoption.

Table 3. Qualitative Themes, Subthemes and Implications for the Framework.

Theme	Subthemes	Framework Implication
Clinical workflow alignment	Early diagnosis pathways; radiologist workload; reporting integration	AI tools should support clinical decision-making without disrupting routine radiology practice.
Technical integration and interoperability	PACS/RIS compatibility; metadata standards; distributed retrieval	Deployment must address data flow, interoperability, and technical reliability.
Governance and regulatory compliance	Regulatory requirements; data privacy; cybersecurity; AI ethics	Implementation should incorporate accountable governance and risk controls.
Organizational readiness	Infrastructure maturity; workforce skills; change management	Healthcare facilities require readiness assessment and capacity-building before deployment.
Consultancy requirements	Readiness assessment; implementation roadmap; evaluation metrics	A structured consultancy process can reduce fragmented or inconsistent adoption.

Note. Themes were derived from semi-structured interviews with expert validators.

Descriptive Statistics

Descriptive statistics of the 14 validation items are shown in Table 4. Expert consensus for the quality of the proposed work presented on the framework was robust, with means of all items over 4.29.

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Item	Mean	SD	Minimum	Maximum
C1	4.47	0.62	3	5
C2	4.41	0.71	3	5
C3	4.53	0.62	3	5
R1	4.35	0.70	3	5
R2	4.47	0.62	3	5
R3	4.41	0.62	3	5
CP1	4.35	0.70	3	5
CP2	4.29	0.77	3	5
CP3	4.41	0.62	3	5
P1	4.47	0.62	3	5
P2	4.53	0.62	3	5
P3	4.41	0.62	3	5
O1	4.47	0.62	3	5
O2	4.53	0.62	3	5

Note. N = 17. Responses were rated from 1 = strongly disagree to 5 = strongly agree.

Table 4. Summary statistics for the validation items

Composite Scores at the Construct-Level. Composite means were calculated as the average values of the items under each construct. All constructs were scored extremely highly showing expert support of the framework.

Table 5. Composite Scores for Framework Evaluation Constructs

Construct	Composite Mean	Interpretation
Clarity	4.47	Very high
Relevance	4.41	Very high
Completeness	4.35	Very high
Practicality	4.47	Very high
Overall evaluation	4.50	Very high

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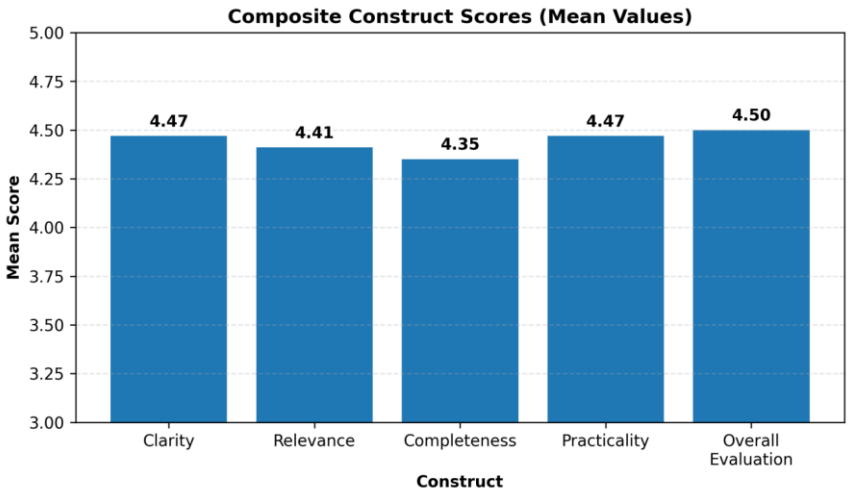

Note. Composite means were computed by averaging the items under each construct.

Figure 1 provides a visual summary of the composite mean scores.

Reliability Analysis.

The Cronbach's alpha values varied from 0.81 to 0.92, indicating strong to excellent internal consistency across all constructs.

Table 6. Results of Cronbach's Alpha Reliability.

Construct	Cronbach's Alpha	Interpretation
Clarity	**0.84**	**Strong reliability**
Relevance	**0.89**	**Strong reliability**
Completeness	**0.81**	**Strong reliability**
Practicality	**0.86**	**Strong reliability**
Overall evaluation	**0.92**	**Excellent reliability**

Note. Cronbach's alpha values above 0.70 indicate acceptable internal consistency.

Expert Consensus Sum.

The qualitative and quantitative results were similar, indicating strong expert consensus. Experts stressed the need for an organized governance-aware, workflow-sensitive implementation model for AI-driven medical imaging. They rated the framework on their survey to confirm clarity, relevance, completeness, and practicality. While the purposive sample does not imply population-level generalization, the findings offer a credible basis for the platform to be honed and pilot tested by the healthcare ecosystem—especially that of healthcare organizations which are undergoing digital transformation and focused on expanding early diagnosis via AI-enabled imaging.

DISCUSSION

Interpretation of the Key Results.

The results indicate substantial expert support for the consultancy model. The high clarity, practicality, and overall evaluation reviews suggest that for experts, the framework was perceived as understandable, operationally applicable, and useful to steer the adoption of AI medical imaging. The qualitative themes support

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that AI adoption in imaging should be viewed as a cohesive institutional process rather than merely as the acquisition of new technology. This reading is consistent with the literature which reiterates that successful adoption of healthcare AI depends, firstly, on clinical validation and second, on organizational readiness, governance structures, and integration into workflow (Abràmoff et al., 2020; Reddy et al., 2020; Vollmer et al., 2020).

Fit with Medical Imaging AI Literature.

The focus on workflow integration and interoperability aligns well with modern research in radiology AI. Tejani, Cook, et al. (2024) emphasise that standards-based interoperability underpins scalable AI deployment, whereas Willemink et al. (2020) highlight the significance of data prep, annotation quality, and standardization of imaging. PACS/RIS compatibility, metadata standards, and distributed retrieval were similarly found by the experts in this study to be critical implementation issues. These results validate the application of the framework rather than acting as a generic AI adoption checklist; addressing concrete clinical needs and technical imperatives.

Governance and AI Trustworthiness implications.

The governance aspect of the framework is reinforced by the international guidance on trustworthy AI. Principles of transparency, explainability, human oversight, privacy, accountability, and safety are echoed in the world's standards including the WHO guidance on AI ethics (World Health Organization, 2021) and the European Union's Artificial Intelligence Act (European Parliament and Council of the European Union, 2024). These principles are operationalized through readiness assessment, regulatory screening and risk evaluation, validation evidence, post-deployment monitoring and role-based accountability. This establishes an explicit bridge between the ethical principles and applied implementation paths.

Strategic Implications for Digital Transformation Initiatives in Healthcare System Transformation.

The framework is strategically sensitive for healthcare systems, including Saudi Arabia, that are in the midst of digital transformation and value quality improvement, prevention, access, and efficiency priorities (Alasiri & Mohammed, 2022). AI-led imaging can help reach these objectives by being developed as a systematic, evidence-based and clinically accepted process. The expert validation results imply that the framework may aid health care organizations in assessing readiness, preventing piecemeal adherence, and aligning AI application with national digital health goals without the need for institutional consent or access to organization records.

Clinical and Operational Implications.

Clinically, the framework helps early diagnosis by providing guideline for healthcare institutions to choose high-value, evidence-supported and workflow-compatible AI use cases. At an operational level, it defines the roles of radiologists, biomedical engineers, PACS/RIS administrators, digital health officers, governance personnel, and vendors. It also encourages phased implementation—from readiness assessment to pilot testing and continued monitoring. This is consistent with reliable reporting principles (Cruz Rivera et al., 2020; Liu et al., 2020; Mongan et al., 2020; Vasey et al., 2022) and evaluation criteria CLAIM, CONSORT-AI, SPIRIT-AI, and DECIDE-AI.

Limitations. Several limitations can be found within this study.

One, the validation involved 17 experts; this would be adequate for exploratory framework development but not statistical generalization. Second, the study gauged expert perceptions, not real-world clinical outcomes. Third, no imaging data at patient level was analyzed. Fourth, the proposed framework has not been empirically tested with a live implementation pilot among healthcare institutions. Lastly, regulatory and digital health standards change over time, and the framework needs to periodically be updated to ensure its continued relevance.

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Analysis Proposed Consultancy Framework

Supported by a synthesis of literature review, qualitative themes, and quantitative validation findings, the revised consultancy framework is structured into seven planned implementation phases. Each stage, relevant consultancy stage and possible outputs are summarised in Table 7.

Stage	Consultancy Activity	Expected Output
1. Readiness assessment	Assess clinical need, infrastructure, data availability, workforce readiness, governance maturity, and leadership support.	Readiness report and gap analysis
2. Use-case prioritization	Identify high-value imaging use cases linked to early diagnosis, patient safety, workload reduction, or service quality.	Prioritized AI imaging use-case list
3. Evidence and regulatory review	Review validation evidence, regulatory status, vendor documentation, bias risks, and explainability claims.	Evidence and compliance review
4. Data and system integration planning	Map data flow, PACS/RIS integration, DICOM routing, metadata requirements, cybersecurity, privacy, and fallback procedures.	Technical integration plan
5. Clinical validation and pilot deployment	Test the AI tool in a controlled workflow with human oversight, performance monitoring, and user feedback.	Pilot evaluation report
6. Full implementation and change management	Train users, define roles, finalize governance controls, and integrate AI outputs into routine reporting pathways.	Implementation plan and training record
7. Monitoring and continuous improvement	Track performance, safety incidents, bias, workflow impact, user acceptance, and model drift.	Post-deployment monitoring dashboard and review cycle

Note. The framework is intended as an implementation guide for healthcare systems and should be adapted based on local readiness, regulatory context, and policy requirements.

The architecture offers a well-defined step by step pathway for healthcare organizations leading from readiness assessment to use-case selection, integration planning, pilot validation, full deployment, and continued monitoring. The framework is designed as an implementation guide for healthcare systems, and it would likely be adapted to reflect specific local readiness, regulatory context and policy needs. This conceptualization places consultancy as an evidence-informed, governance-aligned, structured process for safe, explainable, and sustainable AI uptake of medical imaging. It is intended to be applicable to health care institutions of all stages of digital maturity, and particularly to ones going through national digital transformation programs.

CONCLUSION AND IMPLICATIONS

Conclusion

This study created and validated a consultancy framework for AI-driven medical imaging implementation in healthcare systems. Expert evaluation performed showed very high ratings for clarity, relevance, completeness, practicality, and overall quality, which were supported by high reliability across all constructs. Qualitative results validated that workflow alignment, PACS/RIS interoperability, governance compliance, organizational readiness, and structured consultancy support are critical for successful adoption of AI in radiology. Using the

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literature reviewed, this framework incorporates clinical, technical, organizational, and governance activities as a staged implementation pathway. It provides an evidence-informed, structured way for healthcare institutions to adopt AI-enabled imaging tools without compromising their credibility and in a safe and accountable way. The framework also assists with diagnosing early and increasing workflow efficiency while contributing to broader digital health transformation objectives, making it adaptable to healthcare contexts where levels of digital maturity may differ.

Recommendations

From the findings above, the following recommendations are presented for healthcare organizations planning the implementation of AI-infused medical imaging. Trial the consultancy framework in healthcare organizations with different levels of digital maturity to assess adaptability and operational feasibility. Establish radiology-specific indicators of AI readiness to guide departments in the path of AI deployment. Set up a governance checklist based on AI ethics guidelines for national, data protection, and health services regulatory requirements. Require detailed vendor evidence reviews prior to procurement, with external validation, regulatory status, integration, cybersecurity, and monitoring plan requirements. Assess post-deployment metrics including reporting turnaround time, diagnostic precision, radiologists workload, user acceptance, and patient safety metrics. Look into privacy preserving implementation models—like federated learning—when building a multiple-site model or distributed data environments are necessary, e.g. for multi-site model development or distributed environments for data processing.

Future Research

Future research needs to evaluate the framework through real world pilot implementations in healthcare facilities before and after the adoption and compare results between pre- and post-adoption. Further research may explore how the framework can apply to other radiology subspecialties, assess cost-effectiveness, and assess long-term clinical and operational implications. Insights on governance models, regulatory evolution and sustainable lifecycle management of AI imaging systems will strengthen the evidence base for responsible AI deployment in healthcare.

Declarations

ACKNOWLEDGMENT

The authors appreciate the expert validators who have shared their professional expertise in radiology workflow, biomedical engineering, PACS/RIS administration, digital health, AI governance, and medical imaging implementation with us. Their expert knowledge was important for the validation and adjustment of the proposed consultancy model.

Author Contributions

Engr. Hazel Galas Lampitoc led conceptualization, framework development, data collection, analysis, and manuscript drafting. Dr. Eduardo R. Yu II supervised, conducted a methodology review, recommended critical revisions, and reviewed and approved the manuscript. Both authors reviewed and approved the final manuscript. Funding. This study did not receive external funding.

Conflict of Interest

The authors declare no conflict of interest. Data Availability. On reasonable request, summary data can be made available anonymously by the corresponding author. The confidentiality limitation prevents dissemination of raw interview transcripts and identifiable expert responses.

Ethics consent and informed consent

The study included expert-opinion validation only and no documentation of patient records, or images of patient clinical problems, or identification of patient health information. Hence, it was classified as minimal-risk or

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exempt research. Participation was voluntary and informed consent was obtained before data collection. Anonymisation of interview data and secure storage of data were maintained for all interview transcripts. They should remain with the institution or journal for institutional confirmation of exemption as needed.

AI Assistance Disclosure

AI-assisted editing was employed only for grammar, clarity, format, and reference alignment. All responsibility for study design, data collection, analysis, interpretation and final manuscript content is still attributable to authors.

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