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Ministry Of Health
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Directorate General of Private Health Establishments

Guidelines for the Use of Artificial Intelligence (AI) in Radiology

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Contents Table:

Acronyms

MOH	Ministry of Health
DGPHE	Directorate General of Private Health Establishments
GUD	Guideline
VERS	version
AI	Artificial Intelligence

Definitions

- Artificial Intelligence (AI): The simulation of human intelligence processes by machines, especially computer systems, to perform tasks such as learning, reasoning, and self-correction.
- Diagnostic Imaging: The use of medical imaging techniques, including X-rays, MRI, CT scans, and ultrasound, to diagnose diseases and conditions.

Chapter 1

1. Introduction

This policy outlines the framework for the implementation and utilization of Artificial Intelligence (AI) in diagnostic imaging across healthcare facilities under the Ministry of Health (MOH), Oman. The objective is to enhance diagnostic accuracy, efficiency, and patient outcomes while ensuring equity, safety, and data confidentiality.

This policy will be reviewed and updated regularly to incorporate new advancements in AI technology and to address emerging challenges and opportunities.

2. Scope

This policy applies to all healthcare institutions, radiology departments, healthcare professionals, and other stakeholders involved in diagnostic imaging services within the MOH.

3. Purpose

To guide the Healthcare Institutions to :

- Improve diagnostic accuracy and reduce human error.
- Enhance the efficiency of imaging workflows.
- Facilitate timely diagnosis and treatment as required by the clinical staffs/committees associated with the project.
- Ensure the ethical use of AI in clinical settings.
- To achieve comprehensive and insightful statistics throughout the AI project lifecycle, supporting stakeholders and business owners in evaluating performance at different stages. This includes detailed reports on system accuracy, clinical outcomes, cost efficiency, and adoption rates. These metrics will help assess the effectiveness of the AI solution in terms of patient care and operational efficiency. These reports must be easily available to all stakeholders through visual dashboards in an accessible format and if required integrated with AlShifa.

Chapter 2

4. Structure

4.1. Principles

4.1.1. Patient Safety: AI tools must prioritize patient safety, with rigorous testing and validation before clinical use.

4.1.2. Transparency: The development, implementation and decision-making process of AI systems should be transparent, with clear documentation and explainability of AI decisions.

4.1.3. Ethical Use: AI applications must adhere to ethical standards, including patient consent, privacy, and data security.

4.1.4. Continuous Monitoring: Regular monitoring and evaluation of AI systems to ensure they function as intended and adapt to new data and clinical insights.

4.1.5. Ensure the AI & all its associated systems are hosted locally in MOH or in MOH approved facilities.

4.1.6. Ensure no data is shared or sent outside the Sultanate of Oman for any purposes

4.1.7. Training of the AI (Machine learning) should be conducted on locally hosted servers using data from the Omani population to ensure the most accurate and relevant diagnostic outcomes, tailored specifically to the health conditions and characteristics of the Omani population.

4.1.8. Patient data anonymization - AI systems must prioritize the anonymization of patient data to protect patient confidentiality and comply with data protection regulations. The system should be designed to support the use of fully anonymized datasets for AI training and analysis, ensuring that no personally identifiable information is stored or accessible unless explicitly authorized. Additionally, AI systems should offer configurations that align with project requirements, including options to prevent the storage or saving of patient data entirely, ensuring that no sensitive data is retained beyond the scope of its intended use.

4.1.9. The AI system must be capable of providing clinical insights and results in standardized units that are widely recognized by international AI systems. For example, it should support the use of BI-RADS scores for breast imaging, Gleason scores for prostate cancer, and other relevant diagnostic units as per international standards. This ensures that results are consistent, interpretable, and comparable across different clinical settings and regions.

4.1.10. The solution must adhere to global health data integration standards, such as DICOM for imaging, HL7/FHIR for clinical data exchange, and Web APIs for secure access to data across platforms. Ensuring compliance with these protocols allows for secure, efficient data transfer and integration with other healthcare systems, both within the MOH and with external healthcare providers.

4.2. Implementation

4.2.1. Needs Assessment: Conduct a thorough needs assessment to identify areas where AI can add value in diagnostic imaging.

4.2.2. Selection of AI Tools: Choose AI tools that are validated, approved by relevant international regulatory bodies like FDA in US, CE in EU etc., and demonstrate proven benefits in diagnostic imaging.

4.2.3. Training and Education: Provide training programs for healthcare professionals on the use of AI tools, including their capabilities, limitations, and ethical considerations.

4.2.4. Integration: Ensure seamless integration of AI tools with existing imaging systems and workflows. The AI solution must offer seamless integration with existing AlShifa and other MOH applications and systems. It should be compatible with approved international standards for integrations such as DICOM, HL7, Web APIs and FHIR, enabling interoperability across different platforms. The solution must allow flexibility in adapting to future MOH application upgrades or changes without requiring significant redevelopment. This ensures that the AI solution can work within the broader ecosystem of MOH's digital health infrastructure.

4.2.5. User-Friendly Interfaces: AI systems should be designed with intuitive, user-friendly interfaces that integrate seamlessly into clinical workflows, minimizing disruptions and enhancing adoption among medical staff.

4.2.6. The AI solution should be scalable, capable of functioning across different healthcare facilities, including clinics, hospitals, and tertiary care centers, regardless of varying IT infrastructure.

4.2.7. Infrastructure requirements should be highlighted and responsibilities for arranging any required infrastructure or resource must be well explained and confirmed to the project representatives during the initial planning phase of the project.

4.3. Licensing and Assessment Pathway

4.3.1. Application for Licensing: AI software companies seeking to deploy their solutions in health facilities must apply to the MOH for an integration testing to validate the solution's integration capabilities with AlShifa and other MOH systems.

4.3.2. Assessment Process: The assessment of AI tools will be conducted collaboratively by the Digital Transformation Department in MOH, the Directorate General of Information Technology (DGIT), and the Radiology Services Committee. Additional technical experts may be consulted as needed.

4.3.3. Role of AI: AI's role in diagnostic imaging is to provide primary readings. The final diagnostic report must be prepared and validated by a competent radiologist.

4.3.4. Legal Responsibility: The legal responsibility for the final diagnostic report lies with the radiologists providing the service and the legal liability agreement should be clearly clarified between all parties and documented well before the project kickoff.

4.4. Data Management

4.4.1. Data Collection: Ensure high-quality data collection processes to train and validate AI models.

4.4.2. Data Privacy: Implement robust data privacy measures to protect patient information. The AI system must strictly comply with data protection laws such as the General Data Protection Regulation (GDPR) and other international privacy standards. All sensitive

health information must be encrypted during transmission and storage, ensuring data is protected against unauthorized access.

4.4.3. Data Sharing: Facilitate secure data sharing among healthcare institutions to improve AI models' performance and generalizability.

4.4.4. Anonymization and De-identification: Data used for AI training and processing must be de-identified to protect patient privacy, especially in research or machine learning model development.

4.5. Monitoring and Evaluation

4.5.1. FDA and CE Approval: AI algorithms and systems must be FDA and CE approved.

4.5.2. Ensure all servers and storage are within the Sultanate of Oman.

4.5.3. Performance Metrics: Establish performance metrics to evaluate the effectiveness and impact of AI tools in diagnostic imaging. Continuous performance monitoring should be mandatory to identify any performance deterioration over time. AI algorithms to be thoroughly evaluated to ensure an optimal balance between sensitivity and specificity, tailored to the specific medical use case.

4.5.4. For critical conditions where early detection is vital (e.g., cancer, cardiovascular diseases), high sensitivity should be prioritized to minimize missed diagnoses. On the contrary, for conditions where false positives may lead to unnecessary interventions or anxiety, higher specificity is crucial. This balance must be consistently validated. (to be Added by DGIT- Added)

4.5.5. Feedback Mechanism: Create mechanisms for continuous feedback from users to identify and address any issues promptly. (to create pathway for trouble shooting penalties and reporting and monitoring)

4.5.6. Regular Audits: Conduct regular audits to ensure compliance with the policy and to make necessary adjustments. Also, the system should maintain detailed logs of its operations, allowing for audit trails that document the AI's decision-making process, user actions, including inputs, outcomes, and overrides by healthcare professionals. (where the end-users or DGIT- Added)

4.5.7. Revalidation process (every two years)

4.6. Ethical Considerations

4.6.1. Informed Consent: Obtain informed consent from patients before using AI-assisted diagnostic tools. Patients should be made aware when AI is being used in their care, and their consent must be obtained. This ensures ethical use of AI in diagnostics or treatment recommendations.

4.6.2. Bias and Fairness: Address potential biases in AI systems to ensure fair and equitable treatment of all patients. AI systems must be designed to minimize biases that could lead to unequal or unfair treatment of patients. There should be scheduled regular reviews of AI models for bias detection and mitigation.

4.6.3. Accountability: Maintain accountability for AI decisions, with human oversight to validate and interpret AI-generated results. The AI system should always allow healthcare professionals to override its decisions. Fail-safe mechanisms should ensure human review, especially in critical care areas where AI decisions carry significant risk.

Chapter 3 :

Responsibilities:

- **MOH shall:**
  Establish governance structures, provide resources, and ensure compliance with the concerned guidelines.
- **Private Healthcare Facilities shall:**
  Implement AI systems, ensure staff training, and monitor the performance of AI tools.
- **Healthcare Professionals shall:**
  Adhere to guidelines, use AI tools responsibly, and report any issues or errors.

Chapter 4 :

Document history and version control table

Version	Description	Author	Review date
1	Initial Release	Medical imaging taskforce in DGPHE	August 2028

References

MOH e-Health strategy

Annexes

Additional Guidelines:

1. Radiologist Oversight: All AI-generated reports should be reviewed and signed off by a radiologist.
2. Teleradiology: Establish agreements based on ethical AI practices.
3. Monitoring: Maintain documentation of ongoing AI tool monitoring.
4. Data Privacy: Implement robust data privacy measures.
5. Validation: Regularly assess AI system accuracy.
6. Collaboration: Work with academic and industry partners for research.
7. Training: Continuous training post-upgrades.
8. Risk Management and Liability: Establish legal protocols and responsibilities.
9. Cost and Resource Allocation: Require AI vendors to provide pricing and resource details.