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Document Type: Policy	Ref No: DHA/HISHD/PP-09	Version Number: 1
Document Title: Artificial Intelligence in the Healthcare	Effective Date: 1/7/2021	Revision Date: 1/7/2026
Ownership: Dubai Health Authority		
Applicability: <ul style="list-style-type: none"> All healthcare facilities and professionals licensed by Dubai Health Authority (DHA), utilizing Artificial Intelligence (AI) in healthcare services. National and locally based international AI developers that utilize Dubai based population or patient clinical and nonclinical data to develop AI solutions. UAE based pharmaceutical manufacturers, health insurers, public health entities utilizing AI solutions for healthcare services in the Emirate of Dubai. All AI solutions used by healthcare researchers involved in human research in the Emirate of Dubai. 		

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1. **Purpose:**

- 1.1. To set out the regulatory requirements for the provision of AI solutions in healthcare.
- 1.2. To set out ethical requirements for AI solutions in healthcare.
- 1.3. To articulate the Emirate's vision for AI in healthcare.
- 1.4. To outline key roles and responsibilities of relevant stakeholders in relation to the development and use of AI in healthcare.

2. **Scope:**

- 2.1. All AI solutions related to healthcare services used by healthcare facilities and professionals, pharmaceutical manufacturers, health insurers, public health entities, researchers within the jurisdiction of Dubai Health Authority (DHA).

3. **Definitions/Abbreviations:**

AI	:	Artificial Intelligence
DHA	:	Dubai Health Authority
HIE	:	Health Information Exchange
HISHD	:	Health Informatics & Smart Health Department
HRS	:	Health Regulation Sector
ICT	:	Information Communication and Technology
KPI	:	Key Performance Indicator
UAE	:	United Arab Emirates

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Artificial Technologies: Artificial intelligence technologies such as machine learning, distributed intelligent systems, Smart medical solutions, smart technologies.

Artificial Intelligence: The mimicking of human cognition in the analysis, presentation, and comprehension of complex medical and healthcare data to solve complex problems automatically. It is an area of computer science that makes it possible for 'machines' to learn from new experiences, adjust outputs and perform human-like tasks. It is generally classified into:

- Narrow AI, which focuses on a specific task, or works within a narrow set of parameters such as reading radiology scans or optimising hospital workflows.
- Strong or general AI, which refers to AI that can learn to do several different tasks.

Artificial Intelligence can incorporate algorithms that do not automatically change over time (fixed algorithms) or algorithms that are automatically and continually updated (adaptive algorithms).

Artificial Intelligence Solution: A product, service, process or decision-making methodology whose operation or outcome is materially influenced by artificially intelligent functional units.

Bias (of an AI solution): Inclination or prejudice for or against one person or group, especially in a way considered to be unfair.

Data Confidentiality: Confidentiality in healthcare refers to the obligation of professionals who have access to patient records or communication to hold that information in confidence. Data Confidentiality deals with protecting against the disclosure of information by ensuring that the data is limited to those authorized or by representing the data in such a way that its semantics remain accessible only to those

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who possess some critical information (e.g., a key for decrypting the enciphered data). In the context of health record information, confidentiality implies controlled access and protection against unauthorized access to, modification of, or destruction of health data.

Data Privacy (or information privacy): Is a branch of data security concerned with the proper handling of data – consent, notice, and regulatory obligations. A major goal of the Data Privacy is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality healthcare and to protect the public's health and wellbeing. Data Privacy strikes a balance that permits important uses of information, while protecting the privacy of people who seek care and healing. More specifically, practical data privacy concerns often revolve around:

- Whether or how data is shared with third parties.
- How data is legally collected or stored.
- Regulatory restrictions such as The General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA).

Data Security: Is standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a healthcare entity. The data security requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

Digital Health Technologies: Applications, programmes and software used in the healthcare systems.

They may be standalone or combined with other products such as medical devices or diagnostic tools or tests.

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End user: Is the person within the health sector (provider of services, insurer, pharmaceuticals manufacturer, patient and/or medical researcher) who ultimately uses AI technology or intends to use AI technology.

Ethics (as applied to AI): The concepts of fairness, accountability, transparency and explainability.

Graceful Degradation: "Graceful degradation" is the ability of a computer, machine, electronic system or network to maintain limited functionality even when a large portion of it has been destroyed or rendered inoperative. The purpose of graceful degradation is to prevent catastrophic failure. Ideally, even the simultaneous loss of multiple components does not cause downtime in a system with this feature. In graceful degradation, the operating efficiency or speed declines gradually as an increasing number of components fail.

Healthcare Activities: For the purpose of this policy, this refers to activities provided or executed by physicians, health professionals in the course of providing a healthcare service, pharmaceutical companies in the course of developing new drugs and researchers in the course of conducting medical research.

Healthcare Facility: A DHA licensed establishment (including any hospital, clinic, surgery, pharmacy, diagnostic centre, and other facility) where healthcare services are provided by healthcare professionals in the Emirate of Dubai.

Healthcare Professional: A healthcare professional who treats or deals with patients in the Emirate of Dubai who is licensed & regulated by DHA.

Machine learning: A subgenre of AI in which computer programs and algorithms can be designed to

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“learn” how to complete a specified task, with increasing efficiency and effectiveness as it develops. Such programs can use past performance data to predict and improve future performance. Machine learning can be used to learn and replicate monotonous actions by the end users.

Patient Safety: Is the prevention of errors and adverse effects to patients associated with healthcare.

Point of Entry of AI: The point into the healthcare process (including research and innovation) where the AI use must commence.

Safety and security: All digital technologies used in the delivery of healthcare require that safety and security be taken into consideration so that no harm is brought to lives or bodies of users or third parties. It must be ensured that all digital technologies used in the delivery of healthcare are dependable and robust.

Supportive Technology: Supportive technology is used by a human to assist in the making of final decisions but does not replace human decision-making. Therefore it requires a human to make final decisions and be responsible for any actions taken by the technology” or similar.

4. Policy Statement:

4.1. Ethics:

4.1.1. All AI solutions for healthcare must conform to international, UAE federal, and Emirate of Dubai information laws, regulations, and guidelines with respect to human values, patient autonomy, people rights, and acceptable ethics, in both the long and short term.

4.1.2. Artificial intelligence solutions for healthcare must be fair and free of bias; and must

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benefit people in society.

4.2. Accountability:

- 4.2.1. Accountability for the outcomes of an AI solution in healthcare must be agreed between designer, researcher, developer, operators/commissioners, and end users.
- 4.2.2. Researchers and developers of AI solutions must be accountable to end users.
- 4.2.3. AI solutions for healthcare must have built-in appeals procedures whereby users can challenge significant decisions.

4.3. Transparency:

- 4.3.1. AI solution developers must build systems whose failures can be traced, diagnosed, and controlled.
- 4.3.2. All AI solutions for healthcare must contain disclosure including:
 - a. Which functions and features are AI-enabled.
 - b. How AI solution was validated.
 - c. Which data sets were/must be used.
 - d. What the relevant outcomes were/must be expected.
 - e. What the role of the healthcare professional is in making a final decision.

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- f. What type of algorithm is being developed or deployed.
- g. The ethical examination of how the data is used.
- h. How its performance must be validated.
- i. How the AI solution must be integrated into healthcare provision.
- j. The limitations of the data used and algorithms deployed.

4.3.3. All AI solutions for healthcare must go through independent validation by a competent third party.

4.4. Safety and Security:

- 4.4.1. AI solutions for healthcare must be safe, secure and supervised/monitored by end users.
- 4.4.2. AI solutions for healthcare that may directly impact people's lives in a significant way must be designed with utmost care, and such solutions must be able to be overridden or their decisions reversed by designated end users.
- 4.4.3. AI solutions for healthcare must adhere to relevant international, UAE federal, and Emirate of Dubai information security laws, standards and guidelines.

4.5. Privacy:

- 4.5.1. AI solutions for healthcare must adhere to international, UAE federal, and Emirate of

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Dubai laws and standards of data governance and protection of personal information.

4.6. Minimum acceptable requirements for AI tools:

- 4.6.1. Comply with all international, UAE federal, and Emirate of Dubai new and existing related regulatory requirements governing E-Health, Telehealth, Electronic Health Information Exchange (HIE), Data Protection, Data Quality, Privacy, Transparency, Cybersecurity, and Information security.
- 4.6.2. Comply with all Articles detailed within UAE Federal Law No. (2) of 2019 concerning the Use of the Information and Communication Technology in the Area of Health (“ICT Health Law”).
- 4.6.3. Comply with Cabinet resolution No. (40) Of 2019 and Federal Decree-Law No. (4) of 2016, Concerning the Executive Regulation of on Medical Liability and Addendum Regulations and Conditions for Providing Telehealth Services.
- 4.6.4. Comply with UAE federal, and Emirate of Dubai electronic security authority standards and guidelines for cyber security.
- 4.6.5. Comply with the requirements of the Ministry of Health and Prevention for the use of pharmaceuticals, medical devices and medical advertisement.
- 4.6.6. Comply with all UAE federal and Emirate of Dubai human research laws and

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regulations.

- 4.6.7. Comply with "Dubai Electronic Security Centre" requirements.
- 4.6.8. Comply with "Smart Dubai Government" regulations and requirements.
- 4.6.9. Comply with DHA-Dubai health insurance corporation requirements for e-claims, reimbursement and documentations.
- 4.6.10. Comply with all required certification of the AI software and its major upgraded versions from recognized international/local agencies.
- 4.6.11. AI tool must prevent (inadvertent) misuse of AI-enabled solutions; the performance must be monitored in clinical practice, and actual outcomes must be compared to those obtained in training and validation. Any significant discrepancies must call for further inspection.
- 4.6.12. AI tool must include auditable validation statements.
- 4.6.13. AI tool must be equipped with "Graceful Degradation" mechanisms by means of automatic alerts and gradual operation cessation abilities in AI used for healthcare activities in the event of any hardware or software malfunctioning.
- 4.6.14. AI tool must go through repeated cycles of improvements and updates based on continuous feedback from end users on its accuracy. Such feedback must be sent to

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the DHA-HRS (Health Regulation Sector).

4.6.15. AI solutions must utilise and build into the product or innovation, the use of current data and interoperability standards, to ensure it can communicate easily with existing UAE national systems.

4.6.16. Every user must have a keen understanding of the strengths and limitations of a specific AI-enabled solution.

4.6.17. Adverse events should be timely reported to relevant oversight bodies for appropriate investigation and action.

4.7. Developers of AI solutions / AI commissioners for healthcare must:

4.7.1. Define a clear value proposition with a business case highlighting outputs, outcome, benefits of AI solutions and explain how the technology contribute to it.

4.7.2. All technical specifications, possible side effects, and potential hazards should be listed with the products.

4.7.3. State which good practice guidelines or regulation has been adhered to in the appropriate use of data.

4.7.4. Clearly define the KPIs where the product must result in better provision and/or outcomes for end users, in addition to outlining where and how cost savings or

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reductions are likely to be made.

4.7.5. Encourage the development of new ethical guidelines to address emerging issues with the use of AI in healthcare, as needed.

4.7.6. Risks, benefits vs risk analysis is important to be carried out for AI solutions. Developers/AI commissioners must document the risks and benefits, in order to monitor those risks.

4.7.7. Demonstrate how and where the product must add value to people and the healthcare system.

4.7.8. Consider the clinical, practical and emotional factors that might affect uptake, adoption, and ongoing use of AI.

4.8. End users of AI solutions in the Emirate of Dubai must:

4.8.1. Report to DHA-HRS all known or suspected incidents or deficiencies related to AI solutions used in their respective healthcare facility.

4.8.2. Report to DHA-HRS any issues arising from implementation of AI solutions in the healthcare sector that could potentially affect patient safety.

4.8.3. Provide clear guidelines and boundaries on access to and sharing of any patient information to protect confidentiality and ownership of such information.

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- 4.8.4. Ensure education on AI and its effective use to all those involved including patients.
- 4.8.5. Conduct regular audits of AI functionality by independent third party, and reporting to DHA-HRS as needed.
- 4.8.6. Submit end user feedbacks to DHA-HRS and to the manufacturing company.

4.9. Insurers in the Emirate of Dubai must:

- 4.9.1. Comply with UAE federal and Emirate of Dubai laws, DHA-HRS and DHA-Dubai Health Insurance Corporation policies and guidelines.
- 4.9.2. Ensure clear governance on the use of AI in their services.
- 4.9.3. Ensure clarity on the point of entry of AI in its intended use and on the role of the insurer, the role of AI solution, and the boundaries between them.

4.10. DHA-HRS:

- 4.10.1. Must set out a regulatory framework that governs:
 - a. Safety, responsibility of AI use in healthcare, including graceful degradation.
 - b. Privacy and security of AI in healthcare.
 - c. Transparency and oversight of AI in healthcare.
 - d. Ethical implication of AI in healthcare.

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4.10.2. Must monitor compliance of this policy through audit and inspection and through reports received from end users.

- a. Must adopt a framework to evaluate the effectiveness of the use of AI solutions in the healthcare sector include the following domains: Inputs, Activities, Outputs, and Outcomes.

4.10.3. Must develop monitoring and evaluation framework that will be applied to all healthcare AI stakeholders that incorporate AI solutions in their services in the Emirate of Dubai.

4.11. Enforcement, Compliance and Sanctions:

4.11.1. All stakeholders must comply with the terms and requirements of this policy.

4.11.2. DHA-HRS must impose sanctions in relation to any breach of requirements under this policy in accordance with the complaints, investigations, regulatory action and sanctions policy, and proper legal framework executed by specialized committee that includes multi-disciplinary expertise in the field under DHA-HRS.

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