



دائرة الصحة  
DEPARTMENT OF HEALTH

# Policy on Use of Artificial Intelligence (AI) in the Healthcare Sector of the Emirate of Abu Dhabi

Department of Health (DOH) April 2018

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## ABOUT DEPARTMENT OF HEALTH (DOH)

The Department of Health (DOH) is the regulatory body of the health system in the Emirate of Abu Dhabi and seeks excellence in health for the community by regulating and monitoring the health status of the population. DOH defines the strategy for the health system, monitors and analyses the health status of the population and performance of the system. In addition, DOH shapes the regulatory framework for the health system, inspects against regulations, enforces regulations, and encourages the adoption of best practices and performance targets by all health service providers. DOH also drives programs to increase awareness and adoption of healthy living standards among the residents of the Emirate of Abu Dhabi in addition to regulating scope of services, premiums and reimbursement rates of the health system in the Emirate of Abu Dhabi.

The Health System of the Emirate of Abu Dhabi is comprehensive, encompasses the full spectrum of health services and is accessible to all residents of Abu Dhabi. The health system encompasses, providers, professionals, patients, Insurers and the regulator. Providers of health services include public and private services and the system is financed through mandatory health insurance (with the exception to Thiqa) and has three main sources of financing: Employers or Sponsors, the Government and Individuals. The Health Insurance scheme places responsibilities on any Insurer, Broker, Third Party Administrator, Health Provider, Employer, Sponsor (including educational establishments), Limited Income Investors and Insured Persons to participate in the Health Insurance Scheme.

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# 1. Introduction

The UAE government's forward-looking strategy positions the use of Artificial Intelligence (AI) as a priority in all economic sectors.

In terms of healthcare, AI can play a central role in improving evidence-based quality of care, efficiency, effectiveness, safety, access and delivery of healthcare services, and all types of population and patient research. International evidence demonstrates that AI plays a critical role across the health sector including, but not limited to, improving:

- Diagnosis, treatment and prognosis.
- Patient monitoring and Patient Engagement.
- Pharmaceutical manufacturing.
- Research into new treatments and Precision Medicine.
- Targeted population health programs.
- Access to healthcare.
- Billing and insurance processing.

DOH recognizes the central role AI plays and the benefits to be gained from its use in healthcare. It also supports and encourages the development, use and adoption of customized AI technologies and software for healthcare in Abu Dhabi, and seeks to minimize any potential risks to patient safety.

In its capacity as healthcare regulator, DOH must develop regulatory solutions to govern the use of AI in the healthcare sector. It aims to do so in collaboration with key stakeholders such as research centers, AI and data scientists, practitioners, IT infrastructure engineers and others, in various key areas.

## 2. Definitions

| Term                    | Definition  |
|-------------------------|---|
| AI Technologies         | Artificial Intelligence technologies such as machine learning, distributed intelligent systems, expert systems.   |
| Artificial Intelligence | The mimicking of human thought and cognitive processes to solve complex problems automatically <sup>1</sup> .   |
| End-user                | 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.   |
| 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.” <sup>2</sup> |
| 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.  |
| Machine learning        | A subgenre of AI in which computer programs and algorithms can be designed to “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 <sup>3</sup> .   |
| Point of entry of AI    | The point into the healthcare process (including research and innovation) where the AI use will commence.   |
| Expert System           | A computer program capable of performing at the level of a human expert in a narrow domain. Expert systems have five basic components: the knowledge base, the database, the inference engine, the explanation facilities and the user interface <sup>4</sup> .   |
| 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.   |

<sup>1</sup> From Virtual to Reality, Seven Practical Steps to implement AI in Healthcare, Pocket Book, PWC.

<sup>2</sup> Essential Guide Amazon S3 outage: A guide to getting over cloud failures, Tech Target.

<sup>3</sup> From Virtual to Reality, Seven Practical Steps to implement AI in Healthcare, Pocket Book, PWC.

<sup>4</sup> From Virtual to Reality, Seven Practical Steps to implement AI in Healthcare, Pocket Book, PWC.

### **3. Purpose of this Policy**

The purpose of this Policy is to:

- 3.1. Articulate the Emirate's vision for AI in healthcare.
- 3.2. Outline key roles and responsibilities of relevant stakeholders in relation to the use of AI in healthcare.

### **4. Scope**

This Policy applies to:

- 4.1. DOH-licensed Healthcare Providers.
- 4.2. UAE based pharmaceutical manufacturers.
- 4.3. Healthcare Insurers.
- 4.4. Licensed healthcare researchers involved in human research.
- 4.5. Every local, national and locally based international end-user that utilizes Abu Dhabi based population or patient clinical and non-clinical data in AI endeavours, directly or indirectly, or that wishes to use AI in the course of their healthcare-related endeavours.

### **5. Vision, Goal and Guiding Principles**

#### **5.1.Vision**

To encourage the use of AI to enhance the reach, performance and precision of healthcare related services and minimize any potential risks to patient safety.

#### **5.2.Goal**

To encourage the safe and secure use of AI in healthcare management.

### 5.3. Guiding Principles<sup>5,6</sup> for this policy on AI

- 5.3.1. **Transparency:** AI software should be verifiable and explainable in order to make it possible to ascertain the reasons in the event of any system failures.
- 5.3.2. **User Assistance / Supportive technology:** AI should assist users by giving them reasonable opportunities to make intelligent decisions using AI generated probability-based suggestions.
- 5.3.3. **Safety and Security:** AI requires that safety and security be taken into consideration so that AI systems would not harm lives or bodies of users or third parties. They should ensure AI is dependable and robust.
- 5.3.4. **Privacy:** requires that privacy be taken into consideration so that AI would not infringe the privacy rights of users or third parties.
- 5.3.5. **Ethics:** requires that human dignity and individual autonomy be respected in the research and development of AI.
- 5.3.6. **Accountability:** requires that researchers and developers of AI be accountable to users and other stakeholders. AI researchers and developers should explain and disclose relevant information and maintain adequate communications with stakeholders.

## 6. Policy Statement

DOH seeks to maximize the efficiency, effectiveness, quality, sustainability and access-related benefits gained from using AI in healthcare services and minimize any potential risks to safety, outcome, and experience. Role of AI in healthcare service delivery is understood as supportive technology for:

- Healthcare regulator, providers and insurers to enhance data analysis, draw conclusions and support decision-making.
- Healthcare practitioners to improve the specificity of diagnosis and prognosis and to formulate and execute the right treatment plans.
- Encouraging research and development (R&D) into new treatments and precision medicine.

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<sup>5</sup> Policy Issues Towards AI Networking and Guiding Principles of AI Development, Carnegie Endowment for International Peace.

<sup>6</sup> Scherer, "Regulating Artificial Intelligence Systems," 365–366.



## 7. Roles and Responsibilities

### 7.1. In order to achieve the above policy statement, DOH shall set out the following:

#### 7.1.1. A regulatory framework that will govern:

- 7.1.1.1. Safety, responsibility of AI use in healthcare, including graceful degradation.
- 7.1.1.2. Privacy and security of AI in healthcare.
- 7.1.1.3. Transparency and oversight of AI in healthcare.
- 7.1.1.4. Ethical implication of AI in healthcare.<sup>7</sup>

#### 7.1.2. Minimum acceptable requirements for AI tools:

DOH expects AI and its tools introduced in Abu Dhabi for the purpose of healthcare delivery, public health, pharmaceutical production and medical research to be:

##### 7.1.2.1. Robust and responsive as evidenced by:

- 7.1.2.1.1. Certification of the AI software from recognized international agencies & certification of upgraded major versions of the software.
- 7.1.2.1.2. Compliance with ADSSSA regulations<sup>8</sup>.
- 7.1.2.1.3. Auditable validation statements.

##### 7.1.2.2. 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.

##### 7.1.2.3. Exposed to repeated cycles of improvements and updates based on continuous feedback from end-users on its accuracy. Such feedback should be sent to the Drug & Medical Products Regulation Department, DOH and to the manufacturing company.

##### 7.1.2.4. Subjected to audits and examination of AI system by the technology provider and set up by relevant methods.

##### 7.1.2.5. Complying with all the DOH Health Information Exchange Policy, especially in terms of privacy and transparency.

### 7.2. Healthcare End-Users other than Patients shall:

#### 7.2.1. Have in place clear governance on the use of AI.

#### 7.2.2. Provide clarity on the point of entry of AI in any of the uses listed above and on the role of physician or other practitioner as dictated by scope of AI use, the role AI and on the boundaries between them.

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

#### 7.2.4. Ensure education on AI and its effective use to all those involved including patients.

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<sup>7</sup> Human research in healthcare that uses AI must comply with the DOH Human Research Policy in the DOH Regulator Manual

<sup>8</sup> Abu Dhabi Smart Solutions & Services Authority, ADSSSA:

[https://www.abudhabi.ae/cs/groups/public/documents/attachment/mtmz/njg0/~edisp/adsic\\_nd\\_133684\\_en.pdf](https://www.abudhabi.ae/cs/groups/public/documents/attachment/mtmz/njg0/~edisp/adsic_nd_133684_en.pdf)

- 7.2.5. Conduct regular audits of AI functionality by the owning entities and reporting to DOH as needed.
- 7.2.6. Comply with all required certification of the AI software and its major upgraded versions from recognized international agencies.
- 7.2.7. Comply with all National and DOH new and existing related regulatory requirements governing E-Health, HIE, data protection, information security or AI.<sup>9</sup>
- 7.2.8. Educate end-users, including patients, on AI and its effective use.
- 7.2.9. Submit end-user feedback to the Drug & Medical Products Regulation Department, DOH and to the manufacturing company.

### **7.3. Insurers shall:**

- 7.3.1. Comply with DOH requirements for robust and responsive AI.
- 7.3.2. Ensure clear governance on the use of AI in their service.
- 7.3.3. Ensure clarity on the point of entry of AI in its intended use and on the role of the insurer, the role of AI and the boundaries between them.

## **8. Enforcement, Compliance and Sanctions**

DOH-licensed Healthcare Providers, UAE based pharmaceutical manufacturers, healthcare insurers, licensed healthcare researchers involved in human research, every local, national and locally based international end-user that utilizes Abu Dhabi based population or patient clinical and non-clinical data in AI endeavours, directly or indirectly, or that wishes to use AI in the course of their healthcare-related endeavours must comply with the terms and requirements of this Policy.

DOH may impose sanctions in relation to any breach of requirements under this Policy in accordance with the Complaints, Investigations, Regulatory Action and Sanctions Policy, Chapter XI, Healthcare Regulator Manual.

## **9. Monitoring and Evaluation**

A monitoring and evaluation framework involving all DOH-licensed Healthcare Providers, UAE based pharmaceutical manufacturers, healthcare insurers, licensed healthcare researchers involved in human research, every local, national and locally based international end-user that utilizes Abu Dhabi based population or patient clinical and non-clinical data in AI endeavours, directly or indirectly, or that wishes to use AI in the course of their healthcare-related endeavours and DOH will be developed to monitor and evaluate the Policy, and where necessary adopt changes to ensure continuous improvement within the health care system.

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<sup>9</sup> Included but not limited to ADSEC Information Security Standards:

[https://www.abudhabi.ae/cs/groups/public/documents/attachment/mtmz/njg0/~edisp/adsic\\_nd\\_133684\\_en.pdf](https://www.abudhabi.ae/cs/groups/public/documents/attachment/mtmz/njg0/~edisp/adsic_nd_133684_en.pdf)

DOH shall:

- 9.1 Monitor compliance of the Policy through audit and inspection and through reports received from healthcare end-users. A framework shall be adopted to evaluate the effectiveness of the use of AI in the healthcare sector include the following domains:
  - 9.1.1 Inputs.
  - 9.1.2 Activities.
  - 9.1.3 Outputs.
  - 9.1.4 Outcomes.

End-users other than patients and insurers shall:

- 9.2 Report all known or suspected incidents or deficiencies related to AI used in their respective healthcare domain to DOH and other regulatory bodies.
- 9.3 Report to DOH any issues arising from implementation of AI in the healthcare sector that could potentially affect patient safety.