

A Healthy Start to AI Regulation

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The healthcare sector in Abu Dhabi has become subject to regulation on the use of Artificial Intelligence ('AI') technologies that should set a good foundation for promoting efficiency and effectiveness of AI in the medical field locally.

The extent of the innovation in healthcare that will be unlocked by continued advancements in AI is only really just beginning to be explored.

The potential applications for AI technology in the healthcare sector are numerous and exciting. Healthcare providers are exploring the application of AI programs to diagnostics, analysis of lab result and medical record data analysis.

But how exactly do you regulate technology that is always learning and evolving, constantly changing on the fly?

In April 2018, the Department of Health Abu Dhabi ('DOH') issued the Policy on Use of Artificial Intelligence ('AI') in the Healthcare Sector of the Emirate of Abu Dhabi ("Policy")

DOH is the first entity in the region to take this step, and the policy also forms part of the implementation of the UAE's strategy of AI launched in October 2017, which aims at including AI in numerous sectors, including healthcare.

According to a report by Accenture, AI will not only redesign healthcare by enhancing the performance of the healthcare sector but it will also boost the economic growth of the UAE and add US\$182 billion to the national economy by 2035.

The Policy defines AI as 'the mimicking of human thought and cognitive processes to solve complex problems automatically' and "AI Technologies" as "Artificial Intelligence technologies machine learning, distributed intelligent systems, [and] expert systems'.. In other words, computers will be programed to perform tasks that normally require the intervention of a clinician, such as data management, health monitoring, drug creation, and even designing treatment plans.

The Policy's vision statement is 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.

Additionally, the Policy's goal is to encourage the safe and secure use of AI in healthcare management. The Policy applies to:

- all Abu Dhabi licensed health care providers and professionals;
- UAE based Pharmaceutical manufacturers;
- Abu Dhabi based healthcare insurers; and
- Abu Dhabi licensed healthcare researchers involved in human subjects research;
- national and locally based international end-users that utilise, or wish to utilise, Abu Dhabi based population or patient clinical and non-clinical data in AI endeavours, directly or indirectly.

The Policy does leave to some regulatory decisions on a number of key elements to be determined in the future. These mainly include safety, responsibility of AI use, privacy and security, transparency, and ethical implication of AI in healthcare.

Despite this, the essential requirements of an effective AI in healthcare framework are addressed by the Policy.

In particular, the Policy sets out minimum acceptable requirements that the DOH expects for AI (and its tools) introduced in Abu Dhabi, which includes

- certification by recognised international agencies, compliance with ADSSSA regulations, and auditable validation statements.
- being 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. The Policy defines "Graceful Degradation" as "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.
- exposure to repeated cycles of improvements and updates based on continuous feedback from end-users on its accuracy.
- being subjected to audits and examination of AI system by the technology.
- complying with all the DOH Health Information Exchange Policy, especially in terms of privacy and transparency.

A set of requirements for healthcare end-users, other than patients, are also featured. Such users will be required to, among other things;

- have in place clear governance on the use of AI;

- provide clear guidelines and boundaries on access to and sharing of any patient information to protect confidentiality and ownership of such information;
- conduct regular audits of AI functionality and reporting to DOH, and
- comply with all UAE and DOH related regulatory requirements, including those governing e-health, health information exchanges, data protection, information security, and AI.

Any breach of the Policy will lead to appropriate sanctions that the DOH may impose. This could be the result of the implementation of a monitoring and evaluation framework that would target anyone to which this policy applies.

The DOH has also foreseen possible changes and improvement to the Policy when the Department's monitoring and evaluation shows necessity for such steps. Monitoring compliance with the Policy will be carried out through audit inspections and through reports received from healthcare end-users. These will target the evaluation of inputs, activities, outputs and outcomes to be able to determine the effectiveness of the Policy.

End-users, other than patients, will also play a role in this evaluation, since they will be required to report all known or suspected incidents or deficiencies related to AI and any issues arising from its implementation that could affect patient safety.

How exactly this Policy will aid the use of AI in revolutionising the healthcare sector is still to be determined, but what is certain is that the DOH started the necessary steps needed for an AI regulatory framework to be effectively implemented.

The policy reflects DOH's recognition of the critical role AI can play and the benefits to be gained from its use in healthcare. To support and encourage the use of AI in healthcare, clear regulatory frameworks must be created, following which companies can create the compliance structures necessary to ensure smooth and compliant adoption of AI into healthcare.

Further implementing frameworks are expected from the DOH and we will continue to monitor these. Should you require any advice concerning the new AI policy, our [Healthcare Practice Group](#) would be happy to assist.