

Title: Applicable standards for artificial intelligence in healthcare

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Abstract

Artificial intelligence (AI) is being taken into use in various sectors of the society at the moment. The health sector has been interested in its use for a relatively long time. Before 2024, the use of AI has been largely unregulated, but the approval of the European Union AI Act has changed this. The AI Act is to be supported by harmonized standards to be delivered by the joint AI standardization technical committee 21 of CEN and CENELEC. JTC1/SC42 and others have also published many AI standards. The aim of this study is to identify which AI standards are relevant to the health sector, both for the providers of the health AI systems and for the deployers of the AI systems in the health sector.

The method of carrying out the analysis was to attend meetings of the AI standard development organizations and inspect their documents published or under development. The requirements of the AI Act need to be considered, too.

Health delivery organizations could benefit from applying the AI management system standard ISO 42001 and to-be developed AI transparency standards. The providers of the health AI systems have much more work as they need to focus on the harmonized standards to the AI Act, particularly if their product is classified as a medical device. The healthcare specific AI standards will be relevant, too.